EPA Jacket 12455-61
Vol.1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION,
PESTICIDES AND
TOXIC SUBSTANCES

February 21, 2006

I, John Hebert, Insecticide/Rodenticide Branch, Registration Division, Office of Pesticide Programs, Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency ("EPA"), certify that the pesticide product (s) listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the product(s) may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

Registration of this product(s) with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all the laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product(s). Further, the recipient of this letter is on notice that the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify the recipient(s) (i.e., Dominican Republic) of this letter of any change in the status of the registration(s) and/or the product label for the product(s) listed below.

EPA has issued registration numbers for the product(s) listed below to:

Bell Laboratories Inc
3699 Kinsman Blvd
Madison, WI 53704

EPA Registration Number: 12455-61
Name of Product: LIQUA-TOX II

John Hebert
Risk Manager 07
Insecticide/Rodenticide Branch
Registration Division (7505C)

Torill Holm
<tholm@belllabs.com>
02/01/06 09:02 AM

To BettyR Williams/DC/USEPA/US@EPA
cc
bcc
Subject Gold Seal Letters

Dear Betty,

Would you please send one Gold Seal Letter for each of the following Bell Laboratories, Inc. rodenticide registrations. All letters will be used for new
registrations in the Dominican Republic.

Final Rodenticide 12455-90 - JOHN
Final All-Weather Blox 12455-89 - JOHN
Contrac Rodenticide 12455-69

Contrac All-Weather Blox 12455-79 ✓
Contrac All-Weather Cake 12455-34
Fastrac Place Pac 12455-97
Fastrac All-Weather Blox 12455-95
Ditrac All-Weather Cake 12455-5
Ditrac All-Weather Blox 12455-80
Liqua-Tox II
12455-61

Thank you very much.

Torill Holm
International Registration Specialist
Bell Laboratories, Inc.
tel: 608.241.0202 x3085
fax: 608.241.4081
email: tholm@belllabs.com

Bell Laboratories, Inc.
3699 Kinsman Boulevard, Madison, Wisconsin 53704 U.S.A. / 608/241-0202 / Fax: 608/241-4081

January 26, 2005

Daniel B. Peacock, Biologist
Insecticide-Rodenticide Branch
Registration Division (7504C)
United States Environment Protection Agency
Room #258, Crystal Mall #2
1921 Jefferson Davis Hwy.
Arlington, Virginia 22202

RE: 12455-61 Liqua-Tox II

Dear Mr. Peacock:

In compliance with your letter to Craig Riekena, dated September 30 2004, enclosed please find the required revised labels for the above-referenced products.

If there are any concerns, please do not hesitate to contact either Craig or myself at the number above or via email: jabrams@belllabs.com or criekena@belllabs.com.

Thank you for your assistance with our label revisions!

Sincerely,

Joni Abrams
Registration Specialist

/jla
Enclosures as indicated

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or nontarget animals to rodenticides. To help to prevent accidents:

1. Store unused product out of reach of children and pets.
2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by dogs and by children under six years of age, and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from bait stations when they are lifted, units must be secured or otherwise immobilized. Stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, or other potentially destructive animals, or in areas prone to vandalism.
3. Dispose of product container and unused, spoiled, or unconsumed bait as specified on this label.

USE RESTRICTIONS: For control of Norway rats, roof rats and house mice in and around homes, industrial and agricultural buildings, and similar man-made structures. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food. When used in USDA-inspected facilities, this product must be applied in tamper-resistant bait stations. Do not broadcast bait.

SELECTION OF TREATMENT AREAS: Determine areas where rats or mice will most likely find and consume the bait. Generally, these areas are along walls, by gnawed openings, in or beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or their signs have been seen. Protect bait from rain and snow. Remove as much alternative food as possible.

MIXING DIRECTIONS: Wearing waterproof gloves, thoroughly mix contents of one 1.68 fl. oz. package in 1 quart (32 fluid ounces) of water.

APPLICATION DIRECTIONS:

RATS: Provide a minimum of 1 pint (16 fluid ounces) of LIQUA-TOX II in each dispenser (suitably-equipped bait station, chick fount, or other suitable device). If infested area is large, or if rat population appears to be high, use dispensers at several locations. Space dispensers and refill them as needed to ensure that bait is exposed in all infested areas where it can be used without putting nontarget organisms at risk.

Liqua-Tox II

A Concentrate for Preparing Liquid Baits to Kill Norway Rats, Roof Rats, and House Mice

Mix contents of pouch with 1 quart of water.

NOT REVIEWED
In Accordance with PR Notice 82-2
Based on Draft Labeling Dated
SEP 30 2004

ACTIVE INGREDIENT:	
Sodium Salt of Diphacinone	
(CAS #42721-99-3)	0.106%
INERT INGREDIENTS:.....	99.894%
	100.000%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

HAVE LABEL WITH YOU WHEN OBTAINING TREATMENT ADVICE

IF SWALLOWED:

- Call a poison control center, doctor, or 1-877-854-2494 immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor.

IF ON SKIN:

- Wash with plenty of soap and water.

NOTE TO PHYSICIAN OR VETERINARIAN

If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. If ingested, administer Vitamin K_1 intramuscularly or orally as indicated in bishydroxycoumarin overdoses. Repeat as necessary based on monitoring of prothrombin times.

Net Contents: 1.68 fl. oz. (49.68 ml)

Manufactured by:

Bell Laboratories, Inc.
Madison, WI 53704

EPA REG. NO.12455-61

EPA EST. NO. 12455-WI-1

DIRECTIONS FOR USE (Continued from other panel)

APPLICATION DIRECTIONS (Continued from other panel)

MICE: Provide 1/2-pint (8 fluid ounces) placements of LIQUA-TOX II in suitably-equipped bait stations, chick founts, or other appropriate vessels. Place dispensers at intervals of 8 - 12 feet in all infested areas where bait can be used without putting nontarget organisms at risk.

FOLLOW-UP: Replace contaminated or spoiled bait immediately. Collect and properly dispose of dead animals and bait that is no longer needed. Continue treatments as long as target species are being controlled by bait and nontarget species are not at risk.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Keep away from humans, domestic animals and pets. If handled, wear waterproof gloves. Wash thoroughly with soap and water after handling. Exposure during pregnancy should be avoided. Avoid contact with skin, eyes, or clothing.

ENVIRONMENTAL HAZARDS

This product is toxic to fish, birds and other wildlife. Do not apply this product directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Store only in original container in a cool, dry place inaccessible to children and pets. Keep containers closed and away from other chemicals.

DISPOSAL: **If empty:** do not reuse this container. Place in trash or offer for recycling if available. **If partially filled:** Place in trash or call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

WARRANTY: Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and/or handling of this material when such use and/or handling is contrary to label instructions.

101504

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 30, 2004

Bell Laboratories Inc.
3699 Kinsman Boulevard
Madison, WI 53704

300/17 5-768739

Attention: Mr. Craig A. Riekena

Subject: Liqua-Tox® II
EPA Reg. No. 12455-61
Our letter of November 17, 2003
Your letter of June 8, 2004

Purpose The purpose of this submission is to revise your label in response to our previous letter.

Label The labeling submitted with the above letter, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is acceptable, provided you submit one (1) copy of final printed labeling to us, with the following changes, before you ship your product.

1. For non-homeowner sizes (>1 lb), use the following format for your "Storage and Disposal" text:

STORAGE AND DISPOSAL
Do not contaminate water, food or feed by storage or disposal.
Storage: Store ...other chemical.
Pesticide Disposal: Wastes ... disposal facility.
Pesticide Container: Do not ... proper disposal.

Label-continued

2. Begin "**MIXING DIRECTIONS:**" with "Wearing waterproof gloves, thoroughly ... of water.

3. Under "**CAUTION**", revise the text to read:

   CAUTION: Keep away from humans, domestic animals and pets. If handled, wear water-proof gloves. Wash thoroughly with soap and water after handling. Exposure during pregnancy should be avoided. Avoid contact with skin, eyes, or clothing.

Existing stocks Stocks of existing labels may be used for eighteen (18) months.

Consequence for non-compliance If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Questions If you have questions about this letter, please contact me at 703-305-5407 (by phone), 703-305-6596 (by fax), or peacock.dan@epa.gov (by E-Mail).

Sincerely yours,

Daniel B. Peacock, Biologist
Insecticide-Rodenticide Branch
Registration Division (7504C)

Enclosure 1. Stamped label

Letter Dan Peacock, USB Flash Drive, E:\Dan's Office Work\A Flash Drive 1\Diphacinone Sodium Salt\12455-61, revised label, 9-23-2004.wpd

Liqua-Tox II

A Concentrate for Preparing Liquid Baits to
Kill Norway Rats, Roof Rats, and House Mice

Mix contents of pouch with 1 quart of water.

ACTIVE INGREDIENT:	
Sodium Salt of Diphacinone	
(CAS #42721-99-3)	0.106%
INERT INGREDIENTS:.....	99.894%
	100.000%

ACCEPTED
with COMMENTS
In EPA Letter Dated:

SEP 30 2004
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 12455-61

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

HAVE LABEL WITH YOU WHEN OBTAINING TREATMENT ADVICE

IF SWALLOWED:

- Call a poison control center, doctor, or 1-877-854-2494 immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor.

IF ON SKIN:

- Wash with plenty of soap and water.

NOTE TO PHYSICIAN OR VETERINARIAN

If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. If ingested, administer Vitamin K_1 intramuscularly or orally as indicated in bishydroxycoumarin overdoses. Repeat as necessary based on monitoring of prothrombin times.

Net Contents: 1.68 fl. oz. (49.68 ml)

Manufactured by:
Bell Laboratories, Inc.
Madison, WI 53704

EPA REG. NO.12455-61 EPA EST. NO. 12455-WI-1

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or nontarget animals to rodenticides. To help to prevent accidents:

1. Store unused product out of reach of children and pets.
2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by dogs and by children under six years of age, and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from bait stations when they are lifted, units must be secured or otherwise immobilized. Stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, or other potentially destructive animals, or in areas prone to vandalism.
3. Dispose of product container and unused, spoiled, or unconsumed bait as specified on this label.

USE RESTRICTIONS: For control of Norway rats, roof rats and house mice in and around homes, industrial and agricultural buildings, and similar man-made structures. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food. When used in USDA-inspected facilities, this product must be applied in tamper-resistant bait stations. Do not broadcast bait.

SELECTION OF TREATMENT AREAS: Determine areas where rats or mice will most likely find and consume the bait. Generally, these areas are along walls, by gnawed openings, in or beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or their signs have been seen. Protect bait from rain and snow. Remove as much alternative food as possible.

MIXING DIRECTIONS: Thoroughly mix contents of one 1.68 fl. oz. package in 1 quart (32 fluid ounces) of water.

APPLICATION DIRECTIONS:

RATS: Provide a minimum of 1 pint (16 fluid ounces) of LIQUA-TOX II in each dispenser (suitably-equipped bait station, chick fount, or other suitable device). If infested area is large, or if rat population appears to be high, use dispensers at several locations. Space dispensers and refill them as needed to ensure that bait is exposed in all infested areas where it can be used without putting nontarget organisms at risk.

MICE: Provide 1/2-pint (8 fluid ounces) placements of LIQUA-TOX II in suitably-equipped bait stations, chick founts, or other appropriate vessels. Place dispensers at intervals of 8 - 12 feet in all infested areas where bait can be used without putting nontarget organisms at risk.

FOLLOW-UP: Replace contaminated or spoiled bait immediately. Collect and properly dispose of dead animals and bait that is no longer needed. Continue treatments as long as target species are being controlled by bait and nontarget species are not at risk.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Wash thoroughly with soap and water after handling.

ENVIRONMENTAL HAZARDS

This product is toxic to fish, birds and other wildlife. Do not apply this product directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Store only in original container in a cool, dry place inaccessible to children and pets. Keep containers closed and away from other chemicals.

DISPOSAL: **If empty:** do not reuse this container. Place in trash or offer for recycling if available. **If partially filled:** Place in trash or call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

WARRANTY: Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and/or handling of this material when such use and/or handling is contrary to label instructions.

060804

12455 — 61

Issues with Bell Laboratory (Co. No. 12455) and Motomco (Co. No. 3240) Revised Labels Submitted June 8, 2004								
Adm No	**Active**	**Stor/Disp**	**Single Fd**	**Follow-Up**	**First Aid**	**Gloves**	**Use Restriction**	**Other**
3240-17	Diphacinone NA Salt	X			remove box ret inhal st	rem gloves st	ret to prior text	new uses label sent in
3240-28	Vitamin D-3	X						label sent in
3240-42	Vitamin D-3	X						label sent in
12455-5	Diphacinone	X		X		rem gloves st	ret to prior text	
12455-9	Diphacinone							no changes but label sent in
12455-14	Diphacinone	X				rem gloves st	ret to prior text	
12455-15	Warfarin	X				rem gloves st	ret to prior text	
12455-16	Zinc Phosphide				remove box ret inhal st			
12455-17	Zinc Phosphide	X			rem inh and eye irr[1]	rem gloves st	ret to prior text	
12455-18	Zinc Phosphide	X			rem inh & eye irr	rem gloves st	ret to prior text	
12455-19	Diphacinone	X		X		rem gloves st	ret to prior text	
12455-22	Warfarin	X				rem gloves st	ret to prior text	
12455-24	Zinc Phosphide				remove box ret inhal st			
12455-25	Diphacinone							no changes but label sent in
12455-26	Warfarin							no changes but label sent in
12455-29	Diphacinone	X		X				
12455-30	Zinc Phosphide	X			remove box ret inhal st	rem gloves st	ret to prior text	
12455-31	Bromadiolone							no changes but label sent in
12455-34	Bromadiolone	X		X		rem gloves st	ret to prior text	ret sewer use
12455-36	Bromadiolone	X		X				
12455-39	Vitamin D-3	X		X				
12455-56	Diphacinone	X						chg tube text
12455-57	Vitamin D-3	X						
12455-59	Zinc Phosphide	X			remove box ret inhal st	rem gloves st	ret to prior text	

[1]Co wants to remove inhalation and eye irritation statements from 2% bait products, but will retain such statements on 12455-16 (tracking powder) and 12455-24 (tech).

Issues with Bell Laboratory (Co. No. 12455) and Motomco (Co. No. 3240) Revised Labels Submitted June 8, 2004								
Adm No	**Active**	**Stor/Disp**	**Single Fd**	**Follow-Up**	**First Aid**	**Gloves**	**Use Restriction**	**Other**
12455-61	Diphacinone NA Salt	X			remove box ret inhal st	rem gloves st	ret to prior text	
12455-67	Diphacinone	X						add label info
12455-68	Bromadiolone	X						add label info
12455-69	Bromadiolone						ret to prior text	label sent in
12455-70	Bromadiolone							no changes but label sent in
12455-71	Diphacinone							no changes but label sent in
12455-72	Warfarin							no changes but label sent in
12455-75	Bromadiolone	X		X				
12455-76	Bromadiolone	X		X				
12455-77	Warfarin	X				rem gloves st	ret to prior text	
12455-78	Diphacinone	X		X				
12455-79	Bromadiolone	X		X		rem gloves st	ret to prior text	ret sewer use
12455-80	Diphacinone	X		X		rem gloves st	ret to prior text	
12455-81	Diphacinone	X		X				
12455-82	Bromadiolone	X				rem gloves st	ret to prior text	ret sewer use
12455-83	Diphacinone	X		X				
12455-84	Diphacinone	X		X				
12455-85	Zinc Phosphide	X			remove box ret inhal st	rem gloves st	ret to prior text	
12455-86	Bromadiolone	X		X				
12455-88	Brodifacoum							no changes but label sent in
12455-89	Brodifacoum	X		X		rem gloves st	ret to prior text	ret sewer use
12455-90	Brodifacoum	X		X		rem gloves st	ret to prior text	
12455-91	Brodifacoum	X		X				
12455-92	Bromethalin							no changes but label sent in
12455-93	Bromethalin							no changes but label sent in
12455-94	Brodifacoum	X		X				
12455-95	Bromethalin	X				rem gloves st	ret to prior text	ret sewer use

Issues with Bell Laboratory (Co. No. 12455) and Motomco (Co. No. 3240) Revised Labels Submitted June 8, 2004								
Adm No	**Active**	**Stor/Disp**	**Single Fd**	**Follow-Up**	**First Aid**	**Gloves**	**Use Restriction**	**Other**
12455-96	Bromethalin	X				rem gloves st	ret to prior text	
12455-97	Bromethalin	X						
12455-100	Bromethalin	X						
CA-970015 12455-39	Vitamin D-3							no changes but label sent in
MT-890009 12455-17	Zinc Phosphide							no changes but label sent in
OH-850001 12455-17	Zinc Phosphide							no changes but label sent in
OR-990034 12455-17	Zinc Phosphide				remove box ret inhal st			
PA-820016 12455-19	Diphacinone							no changes but label sent in
VA-820015 12455-19	Diphacinone							no changes but label sent in
Totals		41 products	0 products[2]	19 products	10 products[3]	21 products	22 products	25 changes

Dan Peacock, E:\Dan's Office Work\A Flash Drive 1\Bell Labs\Issues with Bell Labs and Motomco Labels, 9-1-2004.wpd

[2] Need to verify that there are no changes made to labels of brodifacoum, bromadiolone, bromethalin, and other actives.

[3] Bell only identified 8 affected products. However, the co may have already made the change in other products.

Bell Laboratories, Inc.
3699 Kinsman Boulevard, Madison, Wisconsin 53704 U.S.A. / 608/241-0202 / Fax: 608/241-3477

8 June 2004

Mr. Daniel Peacock
Insecticide- Rodenticide Branch
Registrations Division (7505C)
United States Environment Protection Agency
Room #258, Crystal Mall #2
1921 Jefferson Davis Hwy.
Arlington, Virginia 22202
peacock.dan.mailgate@epa.gov

Re: Label Amendments

Dear Mr. Peacock:

Per our discussion of 29 April 2004 I am making the following modifications to our product labels. I will address these modifications point by point as listed in my letter to you of 02 April 2004. Please note that I will be working from, as the base format, the current approved language from the labels most recently approved by USEPA.

Registration Numbers of Enclosed and Discussed Labels (three hard copies and one identical pdf copy of each).

12455-005	12455-059 (inner and outer)	12455-088
12455-009	12455-061	12455-089
12455-014	12455-067 (inner and outer)	12455-090
12455-015	12455-068 (inner and outer)	12455-091
12455-016	12455-069	12455-092
12455-017 E-mail 9-9-2004	12455-070	12455-093
12455-018	12455-071	12455-094
12455-019	12455-072	12455-095
12455-022	12455-075	12455-096
12455-024	12455-076	12455-097
12455-025	12455-077 (inner and outer)	12455-100 (inner and outer)
12455-026	12455-078	CA-97-0015
12455-029	12455-079	OH-85-0001
12455-030	12455-080	OR-99-0034
12455-031	12455-081	MT-89-0009
12455-034	12455-082	PA-82-0016
12455-036	12455-083	VA-82-0015
12455-039	12455-084	3240-17
12455-056	12455-085 (inner and outer)	3240-28
12455-057	12455-086	3240-42 (inner and outer)

I have organized these by product type and have applied sticky notes indicating each group.

Storage/Disposal:
Bell agrees with EPA that "Pesticide Storage" be changed on all labels to "Storage" as product is intended to remain in it's delivered packaging. Second, we agree that there needs to be better, more consistent language in this section and to keep with compliance with current Storage and Disposal Guidelines that we would have two specific categories of statement:

For all non-homeowner based products, i.e., technical actives and concentrates, there will be three subheadings: Storage, Pesticide Disposal, and Container Disposal, with the language to remain as approved.

For all homeowner based products (those which could be potentially used around homes), two subheadings will be used: Storage and Disposal, which will be stated according to PR Notice 2001-6 and our current approved language as:

If empty: do not reuse this container. Place in trash or offer for recycling if available.
If partially filled: Place in trash or call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

This has been corrected on the following labels: 12455-5, 14, 15, 17, 18, 19, 22, 29, 30, 34, 36, 39, 56, 57, 59, 61, 67, 68, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 89, 90, 91, 94, 95, 96, 97, 100, 3240-17, 3240-28, 3240-42 41 products affected

Rat and Mouse Statement:
Bell had contested the "but it may take two or more days" portion of the statement. Bell agrees with EPA that the statement, "Norway rats, Roof rats and House Mice usually consume a lethal dose in a single night's feeding, but it may take two or more days from the time of bait consumption for these rodents to die." would remain for the bromethalin baits as approved by EPA. No labels affected.

Bell had also contested the "in a single night's feeding" portion of the statement. Bell agrees with EPA that for the single-feeding baits (bromadiolone, brodifacoum and bromethalin based baits) the statement, "Norway rats, Roof rats and House Mice usually consume a lethal dose in a single night's feeding, but it may take two or more days from the time of bait consumption for these rodents to die." would remain as approved by EPA. No labels affected.

Application Directions/Rats and Mice
Bell agrees with EPA that the subheading "Follow-Up" under the Application Directions section, as approved on several labels, makes more logical sense than a section called "Rats and Mice" and should be changed on all labels to which it apples. Bell has made this EPA recommended update to the following labels: 12455- 05, 19, 29, 34, 36, 39, 75, 76, 78, 79, 80, 81, 83, 84, 86, 89, 90, 91, 94

19 products affected

First Aid Section

The first area of concern was over the EPA request for "boxes" around the First Aid section on a few labels. Bell and EPA agree that "bullet point" First Aid statements are acceptable. These will be used for all labels. Labels for which boxes were removed: 12455- 16, 24, 56

Boxes optional- OK

affected products

The second area of concern was over the EPA addition of inhalation and eye statements, and protective clothing requirements to several of the zinc phosphide labels. Bell and EPA agreed that Bell would submit these labels without these additions and would argue and provide references to submitted data to demonstrate why these statements are not applicable. EPA agreed to consider the argument and review it's relevance in concert with the data. Note: If I can find a supporting review, then I can complete. If not, I will have to reject it.

Zinc Phosphide inhalation

Inhalation: On September 17, 2003 Bell submitted an inhalation study with ZP Tracking Powder to EPA, MRID #46076701. The results of this study demonstrate that ZP Tracking Powder, with 10% zinc phosphide, has no measurable toxicity via inhalation. While Bell will agree to place the inhalation cautions on ZP-80 and ZP Tracking Powder label, due to it's dusty nature, Bell feels that these results and the bait product's solid form make it very clear that no inhalation statements should be expected on the 2% bait labels.

ZP 80 - keep
ZP Tr. Pow - keep
2% remove text

Zinc Phosphide Eye Ir:

Eyes: On June 25, 1999 Bell submitted an eye irritation study with ZP Rodent Bait to EPA, MRID #44860004. The results of this study demonstrate that ZP Baits, with 2% zinc phosphide, are rated Category IV, "Minimally Irritating". Bell feels that this result and the product's solid form make it very clear that no eye irritation hazards exist and the associated statements should not be required, as Category IV does not require any statements. Additionally, Bell has previously submitted to EPA a study, MRID #46044401, demonstrating that the tracking powder also has a rating of only "Minimally Irritating". The ZP-80 label will remain as approved previously by EPA.

ZP-80-Keep
ZP Tracking Powder, remove text

Expanded/Altered Precautionary Statements: based on the above information and that discussed below for dermal toxicity, it is clear that no additional language can be required. As stated above, labels submitted herein have these additional statements removed and are consistent with previously agreed label language.

affected products

This entire argument/section only affects these eight labels: 12455-16, 18, 30, 59, 61, 85, 3240-17, OR-990034

Wearing Gloves:

EPA has added a "Wear gloves if bait must be handled" statement. Bell does not agree that this statement is required under EPA guidelines and is concerned that EPA is taking an approach of requiring statements based upon personal feelings rather than scientifically defensible facts.

Bell and EPA agreed that Bell would submit these labels without this statement and Bell would argue and provide references to submitted data to demonstrate why this statement is not applicable. EPA agreed to consider the argument and review it's relevance in concert with the data.

Scientific Evidence Argument:
Per the EPA Label Review Manual, August 2003 edition, Chapter 7, Precautionary Statements, Table 1: Toxicity Categories; a Acute Dermal toxicity of greater than 5000 mg/Kg is equivalent to a Category IV rating. Further in the same chapter under Table 4 - Typical Statements for Acute Dermal Toxicity, Category IV it is stated that "No statements are required. However, the registrant may choose to use category III labeling." Provided below are the MRID #s and submission dates for Acute Dermal studies for zinc phosphide, bromadiolone, brodifacoum, bromethalin, and diphacinone, all of which demonstrate Acute Dermal toxicity rates above 5000 mg/Kg. Bell did voluntarily add a "wash hands" statement in good faith but we do not feel that the glove statement is warranted. Bell feels that this requirement is unfounded based upon information in the Agency's possession.

We did not conduct an additional Acute Dermal study for the warfarin baits but common sense would lead one to reason that it would also be above 5000 mg/Kg. If the Agency wishes to continue the glove statement requirement for the warfarin baits Bell will comply.

Submitted Studies:
Zinc Phosphide: MRID #45923501, submitted: Aril 25, 2003
Brodifacoum: MRID #45885301, submitted: March 17, 2003
Bromadiolone: MRID #45885201, submitted: March 17, 2003
Bromethalin: MRID #45925501, submitted: April 28, 2003
Diphacinone: MRID #45923601, submitted: May 2, 2003

Real World Evidence Argument:
EPA has expressed concern that, while short term or single use exposure typical for home users may present no dermal hazards, long term or repeated exposure may present a cumulative exposure problem. While this scenario might seem feasible our own real world experience proves otherwise. After all, there is no chance that any pest control operator would ever have the level, extent, or repeated exposure degree that any employee of the bait manufacturing plant would have.

Bell Laboratories, Inc. has been manufacturing the technical actives, concentrates and baits for over 30 years. Bell manufactures over 10,000 lbs. of bait daily. Our employees routinely handle up to several hundred pounds of bait in a single day by hand. While gloves are available, most employees do not wear gloves as matter of choice and no employees wear respirators when handling the solid, dry baits. Despite this potential high level of both dermal and inhalation exposure, there have been no cases of sickness associated with working with these baits. We have nearly a dozen employees who have

been working with these products for over 20 years and they have NEVER shown any signs of associated illness. In addition, we compile poison call reports from throughout the United States and have not come across any confirmed instances of unintentional human toxicity from exposure to any of our baits.

We appreciate what the EPA is trying to accomplish, but there is no scientific evidence or real world justification to believe that unintentional exposure is a concern. The supposed "worst case scenario" is represented every single day in our plant and nothing adverse has come from it.

affected products: This statement has been removed from the following labels: 12455-05, 14, 15, 17, 18, 19, 22, 30, 34, 59, 61, 77, 79, 80, 82, 85, 89, 90, 95, 96, 3240-17

Use Restriction Statement:
Bell had attempted to modify this statement fairly dramatically to bring it more in line with actually, real world use situations. EPA was unable to accepted the scope of these changes at this time and made other changes, making the label unusable. For the time being, Bell and EPA have agreed to return the wording for this section back to that which was previously approved by EPA. This will be dealt with again once EPA, the RRTF and other concerned parties have found a common, agreeable ground and/or a final decision is made. The following labels have been restored: 12455-34, 36, 39, 68, 75, 76, 79, 82, 86, 89, 90, 91, 94, 95, 96, 97, 100 21 products

Sewer Statements:
Bell and EPA agree that for those labels which had cover letters mistakenly asking for the sewer use statement to be removed from one part of the label while remaining under the directions for use will be resubmitted with the statements restored. The following labels have been corrected: 12455-34, 79, 82, 89, 95 5 products

Side Issues: these issues are not in contention. This information is provided to ease review of labels where other, non-related, correction or updates were made.

12455-67 and 12455-68: According to EPA, Bell had submitted these labels with too many unidentified changes and needed to resubmit these with the changes identified. The changes made to the labels are described below:

1) "This station contains enough bait to kill more than one mouse. Refillable using Ditrac (Contrac) All-Weather Blox and Easy Access Key (included)." These statements were added at based upon discussions with EPA.
2) First Aid, Precaution, Environmental, and Storage/Disposal statements have been updated as per current EPA language.
3) Refill directions and associated graphics have been slightly updated based on product opening system being updated.
4) All other parts are the same.

No Problems: The following labels are acceptable to both Bell with changes requested by EPA. In other words, these have no issues and submitted to allow EPA to have and stamp labels which are correct without need for further comment: 12455-09, 25, 26, 31, 70, 72, 71, 88, 92, 93, CA970015, OH850001, MT890009, PA820016, VA820015 15 products

12455-17: As discussed via phone, separate from the issues above, the use sites have been updated as per the IR-4. The wording used in these sections is consistent with that approved on the HACCO product label 2393-521 on Sept. 30, 2003. This is not an issue for discussion. } new uses

12455-56: Separate from the above issues; under Selection of Treatment Areas it states, "...use suitable cardboard tubes or wooden tunnels securely attached to rafter..." I have had numerous pest control operators (this is a restricted use tracking powder) tell me that they have no idea what a "wooden tunnel" is and they use PVC, sheet metal, and cardboard tubes, pretty much in that order of preference. Bell has modified this part of this sentence to read "...use suitable PVC, sheet metal, cardboard, or similar rigid tubing securely attached to the rafter..." Bell feels that this change does not alter the use pattern of the product in any way and is a change which simply keeps up with the reality of the times.

Dan, I know that this quite a lot. Hopefully this organization is useful and we will be able to complete this by early September, before the next renewal period. If you need me to provide clarification or whatever please do not hesitate to contact me.

Sincerely,

Craig A. Riekena
Compliance Manager
Bell Laboratories, Inc.
criekena@belllabs.com

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

November 17, 2003

Bell Laboratories Inc.
3699 Kinsman Boulevard
Madison, WI 53704

300
17

5-74728

Attention: Mr. Craig A. Riekena

Subject: Liqua-Tox® II
EPA Reg. No. 12455-61
Your amended application of September 19, 2003

Purpose The purpose of this submission is to revise your label in accordance with PR Notices 2001 and 2001-6 and to make other minor changes.

Label review The labeling submitted with the above letter, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is acceptable, provided you submit one (1) copy of final printed labeling to us, with the following changes, before you ship your product.

1. On the Front Panel, under "Liqua-Tox", add:

   A Concentrate for Preparing Liquid Baits to Kill Norway Rats, Roof Rats, and House Mice

2. Change "**RATS & MICE**" to "**FOLLOW-UP**".

3. Begin "**MIXING DIRECTIONS:**" with "Wearing waterproof gloves, thoroughly ... of water.

Label review-continued

4. Revise "**CAUTION**" as follows:

   Harmful if swallowed or absorbed through the skin. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wear waterproof gloves when handling the concentrate or liquid bait. Wash thoroughly with soap and water after handling.

5. Modify the "First Aid" section as indicated in Enclosure 1.

Existing stocks

Stocks of existing labels may be used for eighteen (18) months.

Consequence for non-compliance

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Questions

If you have questions about this letter, please contact me at 703-305-5407 (by phone), 703-305-6596 (by fax), or peacock.dan@epa.gov (by E-Mail).

Sincerely yours,

Daniel B. Peacock, Biologist
Insecticide-Rodenticide Branch
Registration Division (7504C)

Letter

Dan Peacock, Disk128,A:\NA Salt of Diphacinone\12455-61, revised label, 10-28-2003.wpd

Enclosure 1. Suggested First Aid Text for EPA Reg. No. 12455-61.

FIRST AID Have label with you when obtaining treatment advice.	
If swallowed	•Call a poison control center, doctor, or 1-877-854-2494 immediately for treatment advice. •Have person sip a glass of water if able to swallow. •Do not induce vomiting unless told to do so by the poison control center or doctor.
If on skin or clothing	•Take off contaminated clothing. •Rinse skin immediately with plenty of water for 15-20 minutes. •Call a poison control center, doctor, or 1-877-854-2494 immediately for treatment advice.
If in eyes	•Hold eye open and rinse slowly and gently with water for 15-20 minutes. •Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. •Call a poison control center, doctor, or 1-800-xxx-xxxx immediately for treatment advice.
NOTE TO PHYSICIAN OR VETERINARIAN If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. If ingested, administer Vitamin K_1 , intramuscularly or orally . Repeat as necessary based on monitoring of prothrombin times.	

Liqua-Tox II

Mix contents of pouch with 1 quart of water.

ACTIVE INGREDIENT:	
Sodium Salt of Diphacinone	
(CAS #42721-99-3)	0.106%
INERT INGREDIENTS:.....	99.894%
	100.000%

ACCEPTED
with COMMENTS
In EPA Letter Dated:
NOV 17 2003

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.
12455-61

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

HAVE LABEL WITH YOU WHEN OBTAINING TREATMENT ADVICE

IF SWALLOWED:

- Call a poison control center, doctor, or 1-877-854-2494 immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor.

IF ON SKIN:

- Wash with plenty of soap and water.

NOTE TO PHYSICIAN OR VETERINARIAN

If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. If ingested, administer Vitamin K_1 intramuscularly or orally as indicated in bishydroxycoumarin overdoses. Repeat as necessary based on monitoring of prothrombin times.

Net Contents: 1.68 fl. oz. (49.68 ml)

Manufactured by:
Bell Laboratories, Inc.
Madison, WI 53704

EPA REG. NO.12455-61 EPA EST. NO. 12455-WI-1

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or nontarget animals to rodenticides. To help to prevent accidents:

1. Store unused product out of reach of children and pets.
2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by dogs and by children under six years of age, and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from bait stations when they are lifted, units must be secured or otherwise immobilized. Stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, or other potentially destructive animals, or in areas prone to vandalism.
3. Dispose of product container and unused, spoiled, or unconsumed bait as specified on this label.

USE RESTRICTIONS: For control of Norway rats, roof rats and house mice in and around homes, industrial and agricultural buildings, and similar man-made structures. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food. When used in USDA-inspected facilities, this product must be applied in tamper-resistant bait stations. Do not broadcast bait.

SELECTION OF TREATMENT AREAS: Determine areas where rats or mice will most likely find and consume the bait. Generally, these areas are along walls, by gnawed openings, in or beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or their signs have been seen. Protect bait from rain and snow. Remove as much alternative food as possible.

MIXING DIRECTIONS: Thoroughly mix contents of one 1.68 fl. oz. package in 1 quart (32 fluid ounces) of water.

APPLICATION DIRECTIONS:

RATS: Provide a minimum of 1 pint (16 fluid ounces) of LIQUA-TOX II in each dispenser (suitably-equipped bait station, chick fount, or other suitable device). If infested area is large, or if rat population appears to be high, use dispensers at several locations. Space dispensers and refill them as needed to ensure that bait is exposed in all infested areas where it can be used without putting nontarget organisms at risk.

MICE: Provide 1/2-pint (8 fluid ounces) placements of LIQUA-TOX II in suitably equipped bait stations, chick founts, or other appropriate vessels. Place dispensers at intervals of 8 - 12 feet in all infested areas where bait can be used without putting nontarget organisms at risk.

RATS & MICE: Replace contaminated or spoiled bait immediately. Collect and properly dispose of dead animals and bait that is no longer needed. Continue treatments as long as target species are being controlled by bait and nontarget species are not at risk.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Wash thoroughly with soap and water after handling.

ENVIRONMENTAL HAZARDS

This product is toxic to fish, birds and other wildlife. Do not apply this product directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store only in original container in a cool, dry place inaccessible to children and pets. Keep containers closed and away from other chemicals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be placed in trash or delivered to an approved waste disposal facility.

CONTAINER DISPOSAL: Do not reuse empty container. Dispose of empty container by placing in trash, at an approved waste disposal facility or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. Call your local waste agency for any questions on proper disposal.

WARRANTY: Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and/or handling of this material when such use and/or handling is contrary to label instructions.

091703

Liqua-Tox II

3 7 3

Mix contents of pouch with 1 quart of water.

ACTIVE INGREDIENT:	
Sodium Salt of Diphacinone; (2-Diphenylacetyl-1,3-indandione) ...	0.108%
INERT INGREDIENTS	99.892%
TOTAL	100.000%

KEEP OUT OF REACH OF CHILDREN
CAUTION

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help to prevent accidents:

1. Store product not in use in a location out of reach of children and pets.
2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations equipped for dispensing liquid rodenticide baits. These stations must be resistant to destruction by dogs and by children under six years of age, and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are filled, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, or other potentially destructive animals, or in areas prone to vandalism.
3. Dispose of product container and unused, spilled, and unconsumed bait as specified on this label.

USE RESTRICTIONS: This product may be used to control Norway rats (*Rattus norvegicus*), roof rats (*R. rattus*), and house mice (*Mus musculus*) in homes; in industrial, agricultural, and commercial buildings; and in similar manmade structures. Do not use LIQUA-TOX II in any area where there is a possibility of contaminating food or surfaces that come in direct contact with food.
MIXING DIRECTIONS: Thoroughly mix contents of one 1.69 fl. oz. package in 1 quart (32 fluid ounces) of water.
SELECTION OF TREATMENT AREAS: Determine areas where rats and mice will most likely find and consume bait. Generally, these areas are along walls, by gnawed openings, beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or their signs have been seen.

APPLICATION DIRECTIONS

RATS: Provide a minimum of 1 pint (16 fluid ounces) of LIQUA-TOX II in each dispenser (suitably-equipped bait station, chick fount, or other suitable device). If infested area is large, or if rat population appears to be high, use dispensers at several locations. Space dispensers and refill them as needed to ensure that bait is exposed in all infested areas where it can be used without putting nontarget organisms at risk.
MICE: Provide 1/2-pint (8 fluid ounces) placements of LIQUA-TOX II in suitably-equipped bait stations, chick founts, or other appropriate vessels. Place dispensers at intervals of 9-12 feet in all infested areas where bait can be used without putting nontarget organisms at risk.
RATS & MICE: Replace contaminated or spoiled bait immediately. Collect and properly dispose of dead animals and bait that is no longer needed. Continue treatments as long as target species are being controlled by bait and nontarget species are not at risk.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION: Keep away from humans, domestic animals and pets. If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. Exposure during pregnancy should be avoided. Avoid contact with skin, eyes, or clothing.

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Call a physician or Poison Control Center immediately. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.
IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.
IF ON SKIN: Wash with plenty of soap and water.
NOTE TO PHYSICIAN: If ingested, administer Vitamin K_1 intramuscularly or orally as indicated in bishydroxycoumarin overdoses. Repeat as necessary based on monitoring of prothrombin times.

ENVIRONMENTAL HAZARDS

Keep out of lakes, streams, or ponds. Do not contaminate water by cleaning of equipment or disposal of wastes.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.
STORAGE: Store only in original container, in a dry place inaccessible to children and pets.
PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.
CONTAINER DISPOSAL: Securely wrap original container in several layers of newspaper and discard in trash.

EPA Est. No. 12455-WI-1 EPA Reg. No. 12455-61

NET CONTENTS: 1.69 Fl. Oz. (49.99 ml)

Mfg by
Bell Laboratories, Inc.
Madison, WI 53704 U.S.A.

ACCEPTED
with COMMENTS
In EPA Letter Dated:
OCT 7 1992
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 12455-61

US ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES PROGRAMS
REGISTRATION DIVISION (TS-767)
WASHINGTON, DC 20460

NOTICE OF PESTICIDE: ☐ REGISTRATION ☒ REREGISTRATION

(Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)

EPA REGISTRATION NO.	DATE OF ISSUANCE
12455-61	OCT 7 1992
TERM OF ISSUANCE	
NAME OF PESTICIDE PRODUCT	
Liqua-Tox II	

NAME AND ADDRESS OF REGISTRANT *(Include ZIP code)*

Bell Laboratories, Inc.
3699 Kinsman Boulevard
Madison, WI 53704

S424892 161/18

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Add the phrase, "EPA Registration No. 12455-61" to your label before you release the product for shipment.

3. Submit one copy of your final printed labeling for both the pouch and the outer carton before you release the product for shipment. Refer to the A-79 Enclosure for a further description of final printed labeling.

This registration will be subject to cancellation in accordance with FIFRA sec. 6(e) if you do not comply with these conditions. Your release for shipment of the product constitutes acceptance of these conditions.

☐ ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL	DATE
LAF	OCT 7 1992

EPA Form 8570-6 (Rev. 5-76) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED. *U.S. GPO: 1988-512-018/80303

A stamped copy of the label is enclosed for your records.

RAF

Robert A. Forrest
Product Manager (14)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Enclosures: 1) Stamped label
2) A-79 Enclosure

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 25, 2003

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

CRAIG A. RIEKENA
BELL LABORATORIES INC
3699 KINSMAN BLVD
MADISON, WI 53704

PRODUCT NAME: LIQUA-TOX II
COMPANY NAME: BELL LABORATORIES INC
EPA FILE SYMBOL: 12455-61
EPA RECEIPT DATE: 09/23/03

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 4, at (703) 308-7038.

Sincerely,

Front End Processing Staff
Information Services Branch
Information Resources and Services Division

Bell Laboratories, Inc.

3699 Kinsman Boulevard, Madison, Wisconsin 53704 U.S.A. / 608/241-0202 / Fax: 608/241-4081

September 19, 2003

Mr. Daniel Peacock
Insecticide- Rodenticide Branch
Registrations Division (7505C)
United States Environment Protection Agency
Room #258, Crystal Mall #2
1921 Jefferson Davis Hwy.
Arlington, Virginia 22202
peacock.dan.mailgate@epa.gov

Re: Label Amendments for 12455-X

Dear Mr. Peacock:

As per our discussion of 25 April 2003, please find enclosed the Label Amendment forms, three hard copies and one identical electronic copy, in pdf format on the enclosed CD, for the products listed in the table below. These labels should take precedent over any and all others which have been submitted in the course of compliance with RED or other purposes and which may still be in process at EPA. The naming convention used for the pdf labels on the CD is: registration number-product name-label date.

As we discussed, the rational behind these amended labels is multifold. The Storage and Disposal section has been updated to bring it into compliance with current regulations. The First Aid section has also been updated to properly reflect current language regarding veterinarians, not inducing vomiting, and use of bullet points. Any other changes were made to correct improper or inconsistent language usage. Please note that we have also made a great effort to harmonize these labels so that they should now be identical except where use or target species would require obvious differences.

We hope that you are as pleased with these efforts as we are and we looked forward to your approval. Thank you for your assistance in making this a smooth and successful process.

Sincerely,

Craig A. Riekena
Compliance Manager
Bell Laboratories, Inc.
criekena@belllabs.com

Registration Numbers of Enclosed Labels (three hard copies and one identical pdf copy of each)

1	12455-009	Diphacinone	11	12455-031	Bromadiolone	21	12455-085 (inner and outer label)	
2	12455-015	Warfarin	12	12455-039	Vit D3	22	12455-088	Brodifacoum
3	12455-016	Zinc Phos	13	12455-056	Diphacinone	23	12455-092	Brodifacoum
4	12455-017	Zinc Phos	14	12455-057	Vit D3	24	12455-093	Bromadiolone
5	12455-018	Zinc Phos	15	12455-059 (inner and outer label)		25	CA-97-0015	Vit D3
6	12455-022	NA Salt Warfarin	16	12455-061	Na Salt Diph	26	MT-89-0009	Zinc Phos
7	12455-024	Zinc Phos	17	12455-070	Bromadiolone	27	OH-85-0001	Zinc Phos
8	12455-025	Zinc Phos	18	12455-071	Diphacinone	28	OR-99-0034	Zinc Phos
9	12455-026	Warfarin	19	12455-072	Warfarin	29	PA-82-0016	Diphacinone
10	12455-030	Zinc Phos	20	12455-077 (inner and outer label)		30	VA-82-0015	Diphacinone

Warfarin

Please read Instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] **Registration**
- [x] **Amendment**
- [ ] **Other**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 12455-61
2. EPA Product Manager: Daniel Peacock
3. Proposed Classification: [x] None [ ] Restricted
4. Company/Product (Name): *Liqua-Tox II*
PM#
5. Name and Address of Applicant *(Include ZIP Code)*:
Bell Laboratories, Inc.
3699 Kinsman Blvd
Madison, WI 53704
[ ] *Check if this is a new address*
6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No._____
Product Name_____

Section II

- [x] Amendment - Explain Below
- [ ] Resubmission in response to Agency Letter dated_____.
- [ ] Notification - Explain below.
- [ ] Final printed labels in response to Agency Letter dated _____.
- [ ] "Me Too" Application.
- [ ] Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Amendment to label to meet compliance with PR Notices 2000-1 and 2000-6 and to correct several miscellaneous label language inconsistencies which had crept in over the years. Please see cover letter (attached) dated September 19, 2003 for further details.

Section III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [x] No	[ ] Yes [x] No	[ ] Yes [x] No	[ ] Metal [ ] Plastic [ ] Glass [x] Paper [ ] Other (Specify) _____
* *Certification must be submitted.*	If "yes," Unit Package wgt. / No. per container	If "Yes," Package wgt. / No. per container	

3. Location of Net Contents Information: [x] Label [ ] Container
4. Size(s) of Retail Container: 1.68 fl. oz.
5. Location of Label Directions: [x] On Label [ ] On Labeling accompanying product
6. Manner in Which Label is Affixed to Product: [ ] Lithograph [ ] Paper glued [x] Stenciled [ ] Other (_____)

Section IV

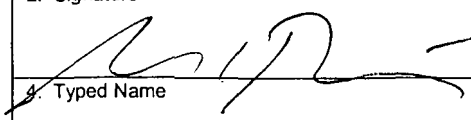
1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this applicaiton.)*

Name	Title	Telephone No. (Include Area Code)
Craig A. Riekena	Compliance Manager	(608) 241-0202

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false for misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
	Compliance Manager
4. Typed Name: Craig A. Riekena	5. Date: September 19, 2003

EPA Form 8570-1 (rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant copy

225747

Approval expires 3-31-89.

US ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS (TS-767)
WASHINGTON, DC 20460

EPA NOTICE OF SUPPLEMENTAL REGISTRATION OF DISTRIBUTOR

(Please read instructions before completing)

H

EPA REGISTRATION NO. OF PRODUCT	DISTRIBUTOR COMPANY NUMBER
2 12455-61 2	3 602

NAME AND ADDRESS OF BASIC REGISTRANT *(print or type; include ZIP code)*

BELL LABORATORIES, INC.
3699 KINSMAN BLVD.
MADISON, WI 53704

CERTIFIED MAIL # P 788 679 523

NAME OF REGISTERED PRODUCT *(basic product name accepted by EPA)*

LIQUA-TOX II

DISTRIBUTOR PRODUCT NAME

Purina® Rat & Mouse Sol-U-Kill

NAME AND ADDRESS OF DISTRIBUTOR *(print or type; include ZIP code)*

Purina Mills, Inc.
P.O. Box 66812
St. Louis, MO 63166-6812

DISTRIBUTOR

We intend to market under the Distributor Product Name and Number specified above, subject to the conditions specified on this form.

SIGNATURE AND TITLE OF DISTRIBUTOR	DATE
Kelly Kraft Kelly Kraft, Product Control Coordinator	3-21-95

REGISTRANT

It is requested that the Registration Record of this jacket include the Distributor Product specified above, subject to the conditions specified on this form.

SIGNATURE AND TITLE OF REGISTRANT	DATE
Victoria J. Dunnum Victoria J. Dunnum Registration Specialist	3/22/95

EPA Form 8570-5 (Rev. 4-83) Previous editions are obsolete.

APPLICANT — Send only original to EPA — Retain copies

INSTRUCTIONS

After a registrant has obtained final registration for the basic product, the registrant may then supplementally register and distribute his/her product. One form must be submitted for each distributor brand and must be signed by the distributor involved. The form must state the basic registration number and the distributor company number.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationary, to the Registration Division to have a number assigned prior to submitting a Distributor Notification to the Agency.

Notification forms must be submitted by the basic registrant. They must have the concurrence and signature of both the registrant and the distributor.

When submitting several forms for the same basic product, submitting them together will facilitate processing.

NOTE: DO NOT submit distributor product labels.

CONDITIONS

1. The distributor product must have the same composition as the basic registered product.
2. The distributor brand product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so no other changes are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must beer the EPA registration number of the basic registered product, followad by a hyphen and the distributor's company number.
6. Distributor products must bear the name end address of the distributor qualified by such terms as "packed for . . .," "distributed by . . ."; or "sold by . . ." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor brand products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

RECEIVED BY EPA REGISTRATION DIVISION ON THE DATE STAMPED BELOW

3.29.95

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

5476087

350
38

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

I, Robert A. Forrest, Product Manager, PM Team 14, Insecticide Rodenticide Branch, Registration Division, Office of Prevention, Pesticide and Toxic Substances, U.S. Environmental Protection Agency, do hereby certify that the pesticide product listed below is currently registered with this Agency under the Federal Insecticide, Fungicide and Rodenticide Act, that the label attached is a true, correct and compared copy of the label accepted by our Agency, and that the product may be sold and marketed in the United States of America for the uses indicated on the label.

The product registration listed below has been issued to:

Bell Laboratories, Inc.
3699 Kinsman Boulevard
Madison, Wisconsin 53704 U.S.A.

EPA Registration Number	Name of Product
12455-61	Liqua-Tox II

IN WITNESS WHEREOF
I have hereunto set my hand
affixed the Seal of the U.S.
Environmental Protection
Agency on this first Day
of December, 1994.

ROBERT A. FORREST

Bell Laboratories, Inc.
3699 Kinsman Boulevard, Madison, Wisconsin 53704 U.S.A. / 608/241-0202 / Fax: 608/241-9631

October 25, 1994

FEDERAL EXPRESS
2514411955

Mr. Robert A. Forrest
Product Manager (14)
Office of Pesticide Programs
Registration Division (H7505C)
U.S. EPA - Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: Certificates for a Registered Product

Dear Mr. Forrest:

Similarly to our previous requests, we are in need of your assistance concerning the registration of our products abroad. Regulation Authorities require that we provide evidence of Bell Laboratories, Inc.'s registration of our products in the U.S.A. They require a letter on official EPA letterhead, signed by EPA personnel, testifying to the fact that Bell Laboratories, Inc.'s products are registered and may lawfully be sold in the United States.

We are in need of a minimum of five (5) letters for the following registered products at your earliest convenience:

	PRODUCT NAME	EPA Reg. No.
1.	ZP Rodent Bait	12455-18
2.	ZP-80 (Technical Zinc Phosphide)	12455-24
3.	Contrac Rat and Mouse Bait	12455-36
4.	Liqua-Tox II	12455-61
5.	Contrac Super-Size Blox	12455-82

If you should have any questions, please contact us. Thank you for your assistance in this matter.

Sincerely,

Bell Laboratories, Inc.

Patrice M. Lottes

Patrice M. Lottes
Registration Assistant

/pml

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

I, Robert A. Forrest, Product, Manager PM Team 14, Insecticide Rodenticide Branch, Registration Division, Office of Pesticide and Toxic Substances, U.S. Environmental Protection Agency do hereby certify that the pesticide product listed below is currently registered with this Agency under the Federal Insecticide, Fungicide and Rodenticide Act and that the label attached is a true, correct and compared copy of the label accepted by our Agency, and that the product may be sold and marketed in the United States of America for the uses indicated on the label.

The product registration listed below has been issued to:

Bell Laboratories, Inc.
3699 Kinsman Boulevard
Madison, Wisconsin 53704

EPA Registration Number	Name of Product
12455-61	Liqua-Tox II

IN WITNESS WHEREOF
I have hereunto set my hand
affixed the Seal of the U.S.
Environmental Protection
Agency on this third Day
of May, 1993

ROBERT A. FORREST

Bell Laboratories, Inc.
3699 Kinsman Boulevard, Madison, Wisconsin 53704 U.S.A. 608/241-0202 Fax: 608/241-9631

April 16, 1993

FEDERAL EXPRESS
 # 2514412106

Mr. Robert A. Forrest
Product Manager (14)
Office of Pesticide Programs
Registration Division (H7505C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: Certificates for Registered Products

Dear Mr. Forrest:

We are in need of your assistance once again concerning the registration of several of our products abroad. Regulation Authorities require that we provide evidence of Bell Laboratories, Inc.'s registration of our products in the U.S.A. They require a letter on official EPA letterhead, signed by EPA personnel, testifying to the fact that Bell Laboratories, Inc.'s products are registered and may lawfully be sold in the United States. These letters must also be notarized.

We have in the past received several of these types of letters from you and have enclosed a sample copy for your convenience. We are in need of a minimum of five (5) letters for each of the following registered products at your earliest convenience:

	PRODUCT NAME	EPA Reg. No.
1.	**DITRAC Super-Size BLOX**	**12455-14**
2.	**CONTRAC Super-Size BLOX**	**12455-82**
3.	**QUINTOX Mouse Seed**	**12455-57**
4.	**DITRAC Tracking Powder**	**12455-56**
5.	**LIQUA-TOX II**	**12455-61**

Thanks in advance. We appreciate your assistance in this matter.

Sincerely,

Bell Laboratories, Inc.

Victoria J. Dunnum

Victoria J. Dunnum
Registration Specialist

VJD:pml
encl.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

COPY

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

I, Marilyn A. Mautz, Acting Product Manager, PM Team 16, Insecticide Rodenticide Branch, Registration Division, Office of Pesticide and Toxic Substances, U.S. Environmental Protection Agency, do hereby certify that the pesticide product listed below is currently registered with this Agency under the Federal Insecticide, Fungicide and Rodenticide Act and that the label attached is a true, correct and compared copy of the label accepted by our Agency, and that the product may be sold and marketed in the United States of America for the uses indicated on the label.

The product registration listed below has been issued to:

Bell Laboratories, Inc.
3699 Kinsman Boulevard
Madison, Wisconsin 53704

EPA Registration Number	Name of Product
12455-36	CONTRAC RAT AND MOUSE BAIT

IN WITNESS WHEREOF
I have hereunto set my hand affixed the Seal of the U.S. Environmental Protection Agency on this twenty-eight day of March, 1991.

marilyn a mautz
MARILYN A. MAUTZ

Commonwealth of Virginia, City/Co. of Arlington
Subscribed and sworn before the this 28th day of Mar. 1991

Notary Public My Comm. Exp 1 Dec. 1994

Printed on Recycled Paper

Bell Laboratories, Inc.
3699 Kinsman Boulevard, Madison, Wisconsin 53704 U.S.A. / 608/241-0202 / Fax: 608/241-9631

E

October 28, 1992

FEDERAL EXPRESS
 # 2514411454

Mr. Robert A. Forrest
Product Manager (14)
Office of Pesticide Programs
Registration Division (H7505C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: LIQUA-TOX II
EPA Reg. No. 12455-61
Your Letter Dated October 7, 1992

Dear Mr. Forrest:

Thank you for your review and for reconsidering the Agency's position on the pouch labeling.

Enclosed as requested please find a copy of the final printed labels for the pouch and for the outer packaging.

We anticipate to market this product in cartons in the following sizes: 4 x 1.68 fl. oz. and 50 x 1.68 fl. oz.

If you should have any questions, please do not hesitate to contact us.

Sincerely,

Bell Laboratories, Inc.

Victoria J. Dunnum
Registration Specialist

VJD:pml

Enclosures

DIRECTIONS FOR USE It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help to prevent accidents:

1. Store product not in use in a location out of reach of children and pets.
2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations equipped for dispensing liquid rodenticide baits. These stations must be resistant to destruction by dogs and by children under six years of age, and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, or other potentially destructive animals, or in areas prone to vandalism.
3. Dispose of product container and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS: This product may be used to control Norway rats (Rattus norvegicus), roof rats (R. rattus), and house mice (Mus musculus) in homes; in industrial, agricultural, and commercial buildings; and in similar manmade structures. Do not use LIQUA-TOX II in any area where there is a possibility of contaminating food or surfaces that come in direct contact with food.
MIXING DIRECTIONS: Using a scissors, cut one 1.68 fl. oz. package where indicated and pour its contents into one quart (32 fl. oz.) of water. Mix LIQUA-TOX II and water thoroughly.
SELECTION OF TREATMENT AREAS: Determine areas where rats and mice will most likely find and consume bait. Generally, these areas are along walls, by gnawed openings, beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or their signs have been seen.

CUT HERE

Liqua-Tox II

Mix contents of pouch with 1 quart of water.

Kills Rats & Mice

ACTIVE INGREDIENT:
Sodium Salt of Diphacinone; (2-Diphenylacetyl-1,3-indandione).....0.106%
INERT INGREDIENTS 99.894%
TOTAL 100.000%

KEEP OUT OF REACH OF CHILDREN

CAUTION

(See back panel for additional precautionary statements.)

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION: Keep away from humans, domestic animals and pets. If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. Exposure during pregnancy should be avoided. Avoid contact with skin, eyes, or clothing.

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Call a physician or Poison Control Center immediately. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.
IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.
IF ON SKIN: Wash with plenty of soap and water.
NOTE TO PHYSICIAN: If ingested, administer Vitamin K, intramuscularly or orally as indicated in bishydroxycoumarin overdoses. Repeat as neccessary based on monitoring of prothrombin times.

ENVIRONMENTAL HAZARDS

Keep out of lakes, streams, or ponds. Do not contaminate water by cleaning of equipment or disposal of wastes.

NET CONTENTS: 1.68 Fl. Oz. (49.68 ml)

Mfg. by:
Bell Laboratories, Inc.
Madison, WI 53704 U.S.A.

EPA Est. No. 12455-WI-1
EPA Reg. No. 12455-61

APPLICATION DIRECTIONS:
RATS: Provide a minimum of 1 pint (16 fluid ounces) of LIQUA-TOX II in each dispenser (suitably-equipped bait station, chick fount, or other suitable device). If infested area is large, or if rat population appears to be high, use dispensers at several locations. Space dispensers and refill them as needed to ensure that bait is exposed in all infested areas where it can be used without putting nontarget organisms at risk.
MICE: Provide 1/2-pint (8 fluid ounces) placements of LIQUA-TOX II in suitably-equipped bait stations, chick founts, or other appropriate vessels. Place dispensers at intervals of 8-12 feet in all infested areas where bait can be used without putting nontarget organisms at risk.
RATS & MICE: Replace contaminated or spoiled bait immediately. Collect and properly dispose of dead animals and bait that is no longer needed. Continue treatments as long as target species are being controlled by bait and nontarget species are not at risk.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.
STORAGE: Store only in original container, in a dry place inaccessible to children and pets.
PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.
CONTAINER DISPOSAL: Securely wrap original container in several layers of newspaper and discard in trash.

10 29 92
EPA

NOT REVIEWED
In Accordance With/IR Notice 82-2
Based on Draft Labeling Dated
10-07-92

JOB DESCRIPTION

COMPANY

PAGE OF PAGES

Liqua-Tox II

Mix contents of pouch with 1 quart of water

Kills Rats & Mice

ACTIVE INGREDIENT:	
Sodium Salt of Diphacinone; (2-Diphenylacetyl-1,3-indandione). ...	0.106%
INERT INGREDIENTS	99.894%
TOTAL	100.000%

KEEP OUT OF REACH OF CHILDREN

CAUTION

(See back panel for additional precautionary statements.)

NET CONTENTS: 4 x 1.68 Fl. Oz. (49.68 ml)

EPA Est. No. 12455-WI-1

EPA Reg. No. 12455-61

Mfg. by:

Bell Laboratories, Inc.
Madison, WI 53704 U.S.A.

10-29-92
EPA

NOT REVIEWED
In Accordance with FR Notice 82-2
Based on Draft Labeling Dated
10-07-92

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help to prevent accidents:

1. Store product not in use in a location out of reach of children and pets.
2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations equipped for dispensing liquid rodenticide baits. These stations must be resistant to destruction by dogs and by children under six years of age, and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, or other potentially destructive animals, or in areas prone to vandalism.
3. Dispose of product container and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS: This product may be used to control Norway rats (Rattus norvegicus), roof rats (R. rattus), and house mice (Mus musculus) in homes; in industrial, agricultural, and commercial buildings; and in similar manmade structures. Do not use LIQUA-TOX II in any area where there is a possibility of contaminating food or surfaces that come in direct contact with food.

MIXING DIRECTIONS: Using a scissors, cut one 1.68 fl. oz. package where indicated and pour its contents into one quart (32 fl. oz.) of water. Mix LIQUA-TOX II and water thoroughly.

SELECTION OF TREATMENT AREAS: Determine areas where rats and mice will most likely find and consume bait. Generally, these areas are along walls, by gnawed openings, beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or their signs have been seen.

APPLICATION DIRECTIONS:

RATS: Provide a minimum of 1 pint (16 fluid ounces) of LIQUA-TOX II in each dispenser (suitably-equipped bait station, chick fount, or other suitable device). If infested area is large, or if rat population appears to be high, use dispensers at several locations. Space dispensers and refill them as needed to ensure that bait is exposed in all infested areas where it can be used without putting nontarget organisms at risk.

MICE: Provide 1/2-pint (6 fluid ounces) placements of LIQUA-TOX II in suitably-equipped bait stations, chick founts, or other appropriate vessels. Place dispensers at intervals of 8-12 feet in all infested areas where bait can be used without putting nontarget organisms at risk.

RATS & MICE: Replace contaminated or spoiled bait immediately. Collect and properly dispose of dead animals and bait that is no longer needed. Continue treatments as long as target species are being controlled by bait and nontarget species are not at risk.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION: Keep away from humans, domestic animals and pets. If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. Exposure during pregnancy should be avoided. Avoid contact with skin, eyes, or clothing.

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Call a physician or Poison Control Center immediately. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

IF ON SKIN: Wash with plenty of soap and water.

NOTE TO PHYSICIAN: If ingested, administer Vitamin K_1 intramuscularly or orally as indicated in bishydroxycoumarin overdoses. Repeat as neccessary based on monitoring of prothrombin times.

ENVIRONMENTAL HAZARDS

Keep out of lakes, streams, or ponds. Do not contaminate water by cleaning of equipment or disposal of wastes.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

STORAGE: Store only in original container, in a dry place inaccessible to children and pets.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Securely wrap original container in several layers of newspaper and discard in trash.

10-29-92

EPA

NOT REVIEWED
In Accordance with FR Notice 52-2
Based on Draft Labeling Dated
10-07-92

10-29-92

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help to prevent accidents:

1. Store product not in use in a location out of reach of children and pets.
2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations equipped for dispensing liquid rodenticide baits. These stations must be resistant to destruction by dogs and by children under six years of age, and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, or other potentially destructive animals, or in areas prone to vandalism.
3. Dispose of product container and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS: This product may be used to control Norway rats (Rattus norvegicus), roof rats (R. rattus), and house mice (Mus musculus) in homes; in industrial, agricultural, and commercial buildings; and in similar manmade structures. Do not use LIQUA-TOX II in any area where there is a possibility of contaminating food or surfaces that come in direct contact with food.

MIXING DIRECTIONS: Using a scissors, cut one 1.68 fl. oz. package where indicated and pour its contents into one quart (32 fl. oz.) of water. Mix LIQUA-TOX II and water thoroughly.

SELECTION OF TREATMENT AREAS: Determine areas where rats and mice will most likely find and consume bait. Generally, these areas are along walls, by gnawed openings, beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or their signs have been seen.

APPLICATION DIRECTIONS:

RATS: Provide a minimum of 1 pint (16 fluid ounces) of LIQUA-TOX II in each dispenser (suitably-equipped bait station, chick fount, or other suitable device). If infested area is large, or if rat population appears to be high, use dispensers at several locations. Space dispensers and refill them as needed to ensure that bait is exposed in all infested areas where it can be used without putting nontarget organisms at risk.

Liqua-Tox II

Mix contents of pouch with 1 quart of water

Kills Rats & Mice

ACTIVE INGREDIENT:	
Sodium Salt of Diphacinone;	
(2-Diphenylacetyl-1,3-indandione). ...	0.106%
INERT INGREDIENTS	99.894%
TOTAL	100.000%

KEEP OUT OF REACH OF CHILDREN
CAUTION

(See right panel for additional precautionary statements)

NET CONTENTS: 50 x 1.68 Fl. Oz. (49.68 ml)

EPA Est. No. 12455-WI-1 EPA Reg. No. 12455-61

Mfg. by:

Bell Laboratories, Inc.
Madison, WI 53704 U.S.A.

MICE: Provide 1/2-pint (8 fluid ounces) placements of LIQUA-TOX II in suitably-equipped bait stations, chick founts, or other appropriate vessels. Place dispensers at intervals of 8-32 feet in all infested areas where bait can be used without putting nontarget organisms at risk.

RATS & MICE: Replace contaminated or spoiled bait immediately. Collect and properly dispose of dead animals and bait that is no longer needed. Continue treatments as long as target species are being controlled by bait and nontarget species are not at risk.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION: Keep away from humans, domestic animals and pets. If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. Exposure during pregnancy should be avoided. Avoid contact with skin, eyes, or clothing.

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Call a physician or Poison Control Center immediately. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

IF ON SKIN: Wash with plenty of soap and water.

NOTE TO PHYSICIAN: If ingested, administer Vitamin K_1 intramuscularly or orally as indicated in bishydroxycoumarin overdoses. Repeat as neccessary based on monitoring of prothrombin times.

ENVIRONMENTAL HAZARDS

Keep out of lakes, streams, or ponds. Do not contaminate water by cleaning of equipment or disposal of wastes.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

STORAGE: Store only in original container, in a dry place inaccessible to children and pets.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Securely wrap original container in several layers of newspaper and discard in trash.

NOT REVIEWED
In Accordance with PR Notice 82-2
Based on Draft Labeling Dated
10-07-92

US ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES PROGRAMS
REGISTRATION DIVISION (TS-767)
WASHINGTON, DC 20460

NOTICE OF PESTICIDE: ☐ REGISTRATION ☒ REREGISTRATION

(Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)

EPA REGISTRATION NO.	DATE OF ISSUANCE
12455-61	OCT 7 1992
TERM OF ISSUANCE	

NAME OF PESTICIDE PRODUCT

Liqua-Tox II

NAME AND ADDRESS OF REGISTRANT *(Include ZIP code)*

Bell Laboratories, Inc.
3699 Kinsman Boulevard
Madison, WI 53704

S424892 161/18

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Add the phrase, "EPA Registration No. 12455-61" to your label before you release the product for shipment.

3. Submit one copy of your final printed labeling for both the pouch and the outer carton before you release the product for shipment. Refer to the A-79 Enclosure for a further description of final printed labeling.

This registration will be subject to cancellation in accordance with FIFRA sec. 6(e) if you do not comply with these conditions. Your release for shipment of the product constitutes acceptance of these conditions.

☐ ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL	DATE
RAF	OCT 7 1992

EPA Form 8570-6 (Rev. 5-76) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED. *U.S. GPO: 1992-[illegible]/80303

A stamped copy of the label is enclosed for your records.

RAF

Robert A. Forrest
Product Manager (14)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Enclosures: 1) Stamped label
2) A-79 Enclosure

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SH248 92 161/18

Ms. Cisse Spragins
Bell Laboratories, Inc.
3699 Kinsman Boulevard
Madison, WI 53704

OCT 7 1992

Dear Ms. Spragins:

Subject: Liqua-Tox II
EPA File Symbol 12455-AR
Your Letter Dated September 1, 1992

The Agency has reviewed the submission referred to above and has the following comments:

1. We have read your letter of September 1, 1992, and have examined the water-filled samples of the type of package that you propose to use for this product and the "squeeze-and-measure" bottle which you provided to us on August 5, 1992. We found the water-filled plastic bag to be stronger and easier to use than we had anticipated. We obtained a clean cut and a reasonably clean pour when we used a scissors to cut the bags at the place indicated on the label.

   As this bag is somewhat resistant but not nearly impervious to punctures, we conclude that it would not be appropriate to ship or market this package unless it were placed within another container. We believe that you already would be likely to use an outer container of some sort unless you were to sell 1.68-fl-oz bags individually.

   Assuming that the pouring behavior of your product is similar to that of the water in the bags that we examined, we have concluded that the 1.68-fl-oz bag may be used for this product, provided that the bags are packed within a labeled outer container. If you elect to sell 1.68-fl-oz bags individually, you still must sell them in some sort of labeled outer container such as a small box. All outer containers used for this product at the point of retail sale must bear complete labels.

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

These labels would bear text identical to that on the label accepted for the bag except for appropriate differences in type sizes and in statements of contents.

We found that the squeeze-and-measure bottle performed well during our first few trials but became erratic thereafter. We encountered the following problems:

a. liquid squirting out when caps were not completely reclosed, and

b. cardboard seals becoming separated from screw caps and adhering to neck finishes, from which they had to be separated manually.

These failures, which would cause exposure of users to the product, were encountered before the container had been emptied of one filling's worth of contents by the squeeze-and-measure method. We concluded, therefore, that this type of packaging would not be preferable to the plastic pouch which you favor. While the pouch and the squeeze-and-measure bottle do not exhaust the entire range of packaging that could be used for LIQUA-TOX II, the pouch was a clear winner in our limited tests of the two.

2. We find the "DIRECTIONS FOR USE" on the proposed label submitted on September 1, 1992, to be generally acceptable. Because we feel that it would be safer and more efficient if bags were cut with scissors than with knives or other implements, we feel that the label should require use of scissors. We conclude, therefore, that your pouches should bear the direction "CUT HERE" at the same spot where this direction appears on the label for "STEARNS EXTRA-STRENGTH CLEANER" and that the "MIXING DIRECTIONS" should be amended to read as follows:

> "MIXING DIRECTIONS: Using a scissors, cut one 1.68 fl. oz. package where indicated and pour its contents into one quart (32 fl. oz.) of water. Mix LIQUA-TOX II and water thoroughly."

Please make these changes to your final printed labels. Submit final printed labels for the pouch and for representative outer packaging and, for our records, indicate the quantities (numbers of pouches per unit) in which you anticipate marketing this product.

With the resolution of the packaging issue discussed above, the requirements for registration of this product have been satisfied except for the outer carton labeling. We will make

submission of that labeling a condition of registration. Therefore, we have enclosed a Notice of Registration and a stamped label with this letter.

Sincerely yours,

RAF

Robert A. Forrest
Product Manager (14)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Enclosures: Notice of Registration
Stamped label

10/07/92:ERICKSON:DISK4:PCK

Liqua-Tox II

Mix contents of pouch with 1 quart of water.

ACTIVE INGREDIENT:	
Sodium Salt of Diphacinone; (2-Diphenylacetyl-1,3-indandione). ...	0.106%
INERT INGREDIENTS	99.894%
TOTAL	100.000%

KEEP OUT OF REACH OF CHILDREN
CAUTION

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help to prevent accidents:

1. Store product not in use in a location out of reach of children and pets.
2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations equipped for dispensing liquid rodenticide baits. These stations must be resistant to destruction by dogs and by children under six years of age, and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, or other potentially destructive animals, or in areas prone to vandalism.
3. Dispose of product container and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS: This product may be used to control Norway rats (Rattus norvegicus), roof rats (R. rattus), and house mice (Mus musculus) in homes; in industrial, agricultural, and commercial buildings; and in similar manmade structures. Do not use LIQUA-TOX II in any area where there is a possibility of contaminating food or surfaces that come in direct contact with food.
MIXING DIRECTIONS: Thoroughly mix contents of one 1.68 fl. oz. package in 1 quart (32 fluid ounces) of water.
SELECTION OF TREATMENT AREAS: Determine areas where rats and mice will most likely find and consume bait. Generally, these areas are along walls, by gnawed openings, beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or their signs have been seen.

APPLICATION DIRECTIONS

RATS: Provide a minimum of 1 pint (16 fluid ounces) of LIQUA-TOX II in each dispenser (suitably-equipped bait station, chick fount, or other suitable device). If infested area is large, or if rat population appears to be high, use dispensers at several locations. Space dispensers and refill them as needed to ensure that bait is exposed in all infested areas where it can be used without putting nontarget organisms at risk.
MICE: Provide 1/2-pint (8 fluid ounces) placements of LIQUA-TOX II in suitably-equipped bait stations, chick founts, or other appropriate vessels. Place dispensers at intervals of 8-12 feet in all infested areas where bait can be used without putting nontarget organisms at risk.
RATS & MICE: Replace contaminated or spoiled bait immediately. Collect and properly dispose of dead animals and bait that is no longer needed. Continue treatments as long as target species are being controlled by bait and nontarget species are not at risk.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION: Keep away from humans, domestic animals and pets. If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. Exposure during pregnancy should be avoided. Avoid contact with skin, eyes, or clothing.

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Call a physician or Poison Control Center immediately. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.
IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.
IF ON SKIN: Wash with plenty of soap and water.
NOTE TO PHYSICIAN: If ingested, administer Vitamin K, intramuscularly or orally as indicated in bishydroxycoumarin overdoses. Repeat as neccessary based on monitoring of prothrombin times.

ENVIRONMENTAL HAZARDS

Keep out of lakes, streams, or ponds. Do not contaminate water by cleaning of equipment or disposal of wastes.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.
STORAGE: Store only in original container, in a dry place inaccessible to children and pets.
PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.
CONTAINER DISPOSAL: Securely wrap original container in several layers of newspaper and discard in trash.

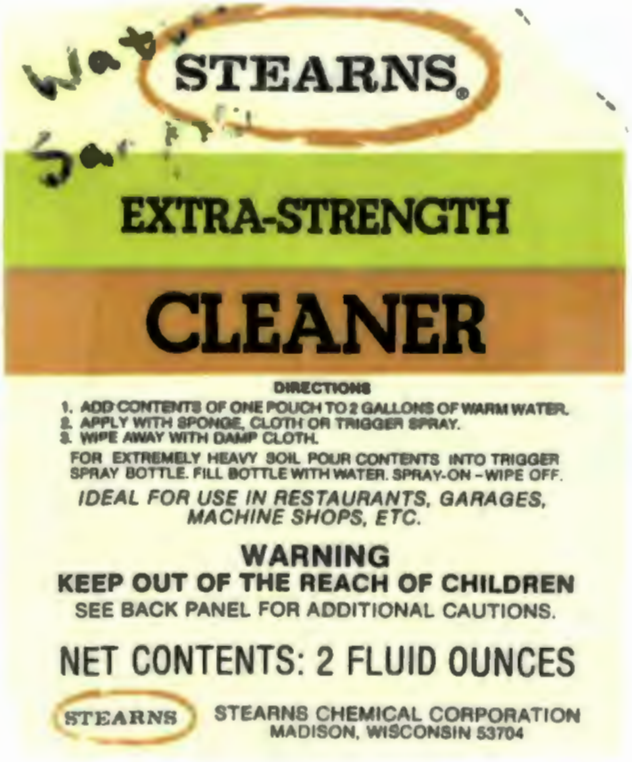
EPA Est. No. 12455-WI-1 EPA Reg. No. 12455-61

NET CONTENTS: 1.68 FL Oz. (49.69 ml)

Mfg. by:
Bell Laboratories, Inc.
Madison, WI 53704 U.S.A.

ACCEPTED
with COMMENTS
in EPA Letter Dated:
OCT 7 1992
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 12455-61

DENSITY
1.003 g/cc


STEARNS
EXTRA-STRENGTH
CLEANER
DIRECTIONS
1. ADD CONTENTS OF ONE POUCH TO 2 GALLONS OF WARM WATER.
2. APPLY WITH SPONGE, CLOTH OR TRIGGER SPRAY.
3. WIPE AWAY WITH DAMP CLOTH.
FOR EXTREMELY HEAVY SOIL POUR CONTENTS INTO TRIGGER SPRAY BOTTLE. FILL BOTTLE WITH WATER. SPRAY-ON – WIPE OFF.
IDEAL FOR USE IN RESTAURANTS, GARAGES, MACHINE SHOPS, ETC.
WARNING
KEEP OUT OF THE REACH OF CHILDREN
SEE BACK PANEL FOR ADDITIONAL CAUTIONS.
NET CONTENTS: 2 FLUID OUNCES
STEARNS
STEARNS CHEMICAL CORPORATION
MADISON, WISCONSIN 53704


CAUTION
AVOID CONTACT WITH SKIN OR EYES - MAY CAUSE IRRITATION. IN CASE OF CONTACT FLUSH THOROUGHLY WITH WATER. DO NOT TAKE INTERNALLY. IF SWALLOWED GIVE AN EGG WHITE OR MILK AND CALL A PHYSICIAN.

Bell Laboratories, Inc.
3699 Kinsman Boulevard, Madison, Wisconsin 53704 U.S.A. / 608/241-0202 / Fax: 608/241-9631

September 1, 1992

FEDERAL EXPRESS
2514411351

Mr. Robert A. Forrest
Product Manager (14)
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division - (H7505C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: LIQUA-TOX II
EPA File Symbol: 12455-AR
Your Letter Dated August 5, 1992 and
Our Meeting of August 5, 1992

Dear Mr. Forrest:

Enclosed, please find four water-filled sample pouches of the size and type proposed for LIQUA-TOX II as per our meeting. Please refer to our submission of December 10, 1990 for information from our packager regarding the construction of the pouch.

We have always felt that the single-dose plastic pouch is a safe and effective way to package a liquid bait concentrate. LIQUA-TOX (containing Sodium Warfarin), EPA Reg. No. 12455-22, has been sold in these pouches for over ten years. During that time, there has not been a single incidence of a leaky or punctured pouch reported to us, nor have we received any complaints regarding the use and safety of opening and mixing the concentrate.

In an effort to be reasonable and comply with the Agency's wishes, we did agree, as you noted, to package the product in a plastic bottle. We then contacted our distributors to find out what type of bottle was considered most convenient by the end-user and had the least problems with leakage. (It has been our experience that bottles with caps are generally much more prone to leaking than sealed pouches.) The bottle which was recommended, and which is currently used for insecticides which are more toxic than the product we are proposing, was the one we presented at our August 5, 1992 meeting. We were quite disappointed with what we considered to be an unreasonable critique of this bottle by the Agency. Hence, we have decided to return to our original position, which also represents our honest feeling on what is most reasonable for this product. That is, that a single-dose plastic pouch is the most effective choice for packaging this product.

A single-dose plastic bottle for this product is completely impractical. If one had a product with several million dollars in annual sales, then one could purchase bottles in large quantities and invest in automated, high-speed packaging equipment which would make the product cost-effective. For a product with potential sales of only about $40,000 annually, packaging it in this manner would be cost-prohibitive. We also honestly feel that a small child would be more apt to be able to open and drink a significant quantity from a small bottle than they would a small plastic pouch of the type we are proposing.

Although the market is small, there are specific instances in which a liquid bait is the best choice for rodent control. Since we endeavor to have a complete line of rodent control products, we desire to have an effective liquid bait product in our line. To our knowledge, we are the only company which currently markets a liquid bait product at all.

Our basic feeling on the matter is that the Agency is over reacting to a perceived problem which has simply not been shown to exist. In summary, we feel that the single-dose plastic pouch is the most reasonable and safest option for this product. We would greatly appreciate your reconsideration.

Enclosed, also, please find five (5) copies of our proposed label for this product, revised as per your above-mentioned letter.

Thank-you for your time and consideration. We look forward to a favorable review.

Sincerely,

Bell Laboratories, Inc.

Cisse W. Spragins, Ph.D.
Technical Director

CWS:pml

Enclosure

Liqua-Tox II

Mix contents of pouch with 1 quart of water.

ACTIVE INGREDIENT:	
Sodium Salt of Diphacinone; (2-Diphenylacetyl-1,3-indandione). ...	0.106%
INERT INGREDIENTS	99.894%
TOTAL	100.000%

KEEP OUT OF REACH OF CHILDREN
CAUTION

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help to prevent accidents:

1. Store product not in use in a location out of reach of children and pets.
2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations equipped for dispensing liquid rodenticide baits. These stations must be resistant to destruction by dogs and by children under six years of age, and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, or other potentially destructive animals, or in areas prone to vandalism.
3. Dispose of product container and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS: This product may be used to control Norway rats (Rattus norvegicus), roof rats (R. rattus), and house mice (Mus musculus) in homes; in industrial, agricultural, and commercial buildings; and in similar manmade structures. Do not use LIQUA-TOX II in any area where there is a possibility of contaminating food or surfaces that come in direct contact with food.

MIXING DIRECTIONS: Thoroughly mix contents of one 1.68 fl. oz. package in 1 quart (32 fluid ounces) of water.

SELECTION OF TREATMENT AREAS: Determine areas where rats and mice will most likely find and consume bait. Generally, these areas are along walls, by gnawed openings, beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or their signs have been seen.

APPLICATION DIRECTIONS

RATS: Provide a minimum of 1 pint (16 fluid ounces) of LIQUA-TOX II in each dispenser (suitably-equipped bait station, chick fount, or other suitable device). If infested area is large, or if rat population appears to be high, use dispensers at several locations. Space dispensers and refill them as needed to ensure that bait is exposed in all infested areas where it can be used without putting nontarget organisms at risk.

MICE: Provide 1/2-pint (8 fluid ounces) placements of LIQUA-TOX II in suitably-equipped bait stations, chick founts, or other appropriate vessels. Place dispensers at intervals of 8-12 feet in all infested areas where bait can be used without putting nontarget organisms at risk.

RATS & MICE: Replace contaminated or spoiled bait immediately. Collect and properly dispose of dead animals and bait that is no longer needed. Continue treatments as long as target species are being controlled by bait and nontarget species are not at risk.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION: Keep away from humans, domestic animals and pets. If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. Exposure during pregnancy should be avoided. Avoid contact with skin, eyes, or clothing.

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Call a physician or Poison Control Center immediately. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

IF ON SKIN: Wash with plenty of soap and water.

NOTE TO PHYSICIAN: If ingested, administer Vitamin K_1 intramuscularly or orally as indicated in bishydroxycoumarin overdoses. Repeat as neccessary based on monitoring of prothrombin times.

ENVIRONMENTAL HAZARDS

Keep out of lakes, streams, or ponds. Do not contaminate water by cleaning of equipment or disposal of wastes.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

STORAGE: Store only in original container, in a dry place inaccessible to children and pets.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Securely wrap original container in several layers of newspaper and discard in trash.

EPA Est. No. 12455-WI-1 EPA Reg. No. 12455-61

NET CONTENTS: 1.68 Fl. Oz. (49.68 ml)

Mfg. by:

Bell Laboratories, Inc.
Madison, WI 53704 U.S.A.

IRB BRANCH REVIEW - TSS

Record Number(s)

D182291

9/8/92 10/7/92

IN _____ OUT _____

EFFICACY

FILE OR REG. NO. 12455-AR

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED 9/2/92

DATE OF SUBMISSION 9/1/92

DATE SUBMISSION ACCEPTED 9/8/92

TYPE PRODUCTS(S): I, D, H, F, N, RX S

DATA ACCESSION NO(S). no new efficacy data

PRODUCT MGR. NO. 14

PRODUCT NAME(S) LIQUA-TOX II

COMPANY NAME Bell Laboratories, Inc.

SUBMISSION PURPOSE registration, settle disputes regarding packaging

CHEMICAL & FORMULATION 0.106% Sodium Salt of Diphacinone liquid concentrate

Efficacy Review: LIQUA-TOX II, 12455-AR
Bell Laboratories, Inc.
Madison, WI 53704

200.0 INTRODUCTION

200.1 Uses

A 1.06% Sodium Salt of Diphacinone liquid concentrate proposed for registration for mixing into water baits for control of Norway rats, roof rats, and house mice

"in homes; industrial, agricultural, and commercial buildings; and in similar man-made structures."

200.2 Background Information

See product jacket, especially efficacy reviews of 6/19/90, 10/19/90, 11/20/90, and 3/7/91. The current submission is a letter of 9/1/92, to which is appended a copy of a revised proposed label. The letter primarily is concerned with issues relating to the packaging of the product. The proposed revised label incorporates the expanded statements on bait protection which appeared in the format labels appended to the Reregistration Eligibility Document (RED) for Warfarin.

201.0 DATA SUMMARY

No new efficacy data were submitted. Efficacy data previously submitted for this product were accepted in the efficacy review of 3/7/91 and in EPA's letter of 8/14/91.

In its letter of 9/4/90, Bell described the packaging to be used for this product as a "3 1/4 inch x 4 1/4 inch pouch containing 1.68 fl. oz. of product." In some cases, these "pouches" would be packed 50 to a carton. It still is not clear whether they would be sold only in 50-pouch lots or whether they would be sold in other ways, including as individual pouches. I became concerned that this type of package could be punctured accidentally and that its contents might be spilled while users (which could include the general public) were attempting to mix baits.

Bell recently provided examples of the type of packaging which it claims to use for this product. The samples were loaded with water and were labeled for "STEARNS EXTRA-STRENGTH CLEANER" rather than for LIQUA-TOX II or any of Bell's other liquid concentrate products.

Robert Forrest (Product Manager 14) and I examined these plastic bags and found them to be far stronger and easier to use and to empty than we had expected. The bags poured nearly empty. It is possible to puncture the bags with the tip of a ballpoint pen, but some effort is required. We concluded that this type of packaging was appropriate for providing measured amounts of concentrate for preparing liquid baits and that container failures in use would be unlikely if a scissors was used to open the packs at the point where the cleaner's label says "CUT HERE." We remained concerned about the possibility of damage to bags in commerce (including in shopping carts) if there were no outer package to protect the plastic bag.

Although Bell previously had indicated that bags of LIQUA-TOX II would be sold in 50-pouch lots packed in a box, Bell has not submitted a label for such a carton.

In her letter of 9/1/92, Cisse Spragins states that Bell believes that this

> ". . . single-dose plastic pouch is the most effective choice for packaging this product."

Dr. Spragins claims that using single-dose bottles would be cost-prohibitive for a specialty product such as this one and that bottles

> ". . . are generally much more prone to leaking than sealed pouches."

Bell provided an example of a two-capped, squeeze-and-measure type of bottle allegedly used for insecticides as a possible alternative package for this product. Our informal testing of this bottle indicated that it worked successfully at first but that accidents occurred upon repeated usage. These accidents included liquid squirting out if one or both of the caps were not screwed on tightly and the separation of the "measure" side's cap from its liner. The liner was left behind on the neck finish and had to be removed by hand and inserted back into the cap, from which it separated once again during the next simulated usage. Our limited experience with the two types of packages suggested to us that Bell's pouch would be safer to handle and use. However, the pouch and the squeeze-and-measure bottle would not exhaust the range of possible packaging for this product.

The use directions on the label submitted on 9/1/92 are acceptable, but the bag's label should indicate that the bags should be cut with a scissors as knives or other implements may result in rougher and more hazardous cutting.

202.0 CONCLUSIONS

1. We have read your letter of September 1, 1992, and have examined the water-filled samples of the type of package that you propose to use for this product and the "squeeze-and-measure" bottle which you provided to us on August 5, 1992. We found the water-filled plastic bag to be stronger and easier to use than we had anticipated. We obtained a clean cut and a reasonably clean pour when we used a scissors to cut the bags at the place indicated on the label.

   As this bag is somewhat resistant but not nearly impervious to punctures, we conclude that it would not be appropriate to ship or market this package unless it were placed within another container. We believe that you already would be likely to use an outer container of some sort unless you were to sell 1.68-fl-oz bags individually.

   Assuming that the pouring behavior of your product is similar to that of the water in the bags that we examined, we have concluded that the 1.68-fl-oz bag may be used for this product, provided that the bags are packed within a labeled outer container. If you elect to sell 1.68-fl-oz bags individually, you still must sell them in some sort of labeled outer container such as a small box. All outer containers used for this product at the point of retail sale must bear complete labels. These labels would bear text identical to that on the label accepted for the bag except for appropriate differences in type sizes and in statements of contents.

   We found that the squeeze-and-measure bottle performed well during our first few trials but became erratic thereafter. We encountered the following problems:

   a. liquid squirting out when caps were not completely reclosed, and

   b. cardboard seals becoming separated from screw caps and adhering to neck finishes, from which they had to be separated manually.

   These failures, which would cause exposure of users to the product, were encountered before the container had been emptied of one filling's worth of contents by the squeeze-and-measure method. We concluded, therefore, that this type of packaging would not be preferable to the plastic pouch which you favor. While the pouch and the squeeze-and-measure bottle do not exhaust the

entire range of packaging that could be used for LIQUA-TOX II, the pouch was a clear winner in our limited tests of the two.

2. We find the "DIRECTIONS FOR USE" on the proposed label submitted on September 1, 1992, to be generally acceptable. Because we feel that it would be safer and more efficient if bags were cut with scissors than with knives or other implements, we feel that the label should require use of scissors. We conclude, therefore, that your pouches should bear the direction "CUT HERE" at the same spot where this direction appears on the label for "STEARNS EXTRA-STRENGTH CLEANER" and that the "MIXING DIRECTIONS" should be amended to read as follows:

> "MIXING DIRECTIONS: Using a scissors, cut one 1.68 fl. oz. package where indicated and pour its contents into one quart (32 fl. oz.) of water. Mix LIQUA-TOX II and water thoroughly."

Please make these changes to your final printed labels. Submit final printed labels for the pouch and for representative outer packaging and, for our records, indicate the quantities (numbers of pouches per unit) in which you anticipate marketing this product.

William W. Jacobs
Principal Specialist: Rodenticides
Insecticide-Rodenticide Branch
October 7, 1992

424364-ØØ

Bell Laboratories, Inc.
3699 Kinsman Boulevard, Madison, Wisconsin 53704 U.S.A. / 608/241-0202 / Fax: 608/241-9631

August 7, 1992

FEDERAL EXPRESS
#2514411336

Mr. Robert A Forrest
Product Manager (14)
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division-(H7505C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: LIQUA-TOX II
EPA File Symbol: 12455-AR
Your letter dated January 21, 1992

Dear Mr. Forrest:

Enclosed please find three (3) copies of the final report for Product Chemistry guidelines 63-17 (Storage Stability) and 63-20 (Corrosion Characteristics). This completes our submission of Product Chemistry in support of this new product.

We look forward to a favorable review.

Sincerely,

Bell Laboratories, Inc.

Victoria J. Dunnum
Registration Specialist

VJD:pml

Enclosures

TRANSMITTAL DOCUMENT:

NAME AND ADDRESS OF SUBMITTER:

Bell Laboratories, Inc.
3699 Kinsman Blvd.
Madison, WI 53704

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED:

40 CFR §158.150 - 190; GRN 63-17 and 63-20
Product Chemistry
Liqua-Tox II, EPA File Symbol: 12455-AR

TRANSMITTAL DATE:

August 7, 1992

LIST OF SUBMITTED STUDIES:

Volume 1: Series 63: Physical and Chemical Characteristics of Liqua-Tox II

42436401

Company Official: Victoria J. Dunnum
Victoria J. Dunnum
Registration Specialist

Company Name: Bell Laboratories, Inc.

Company Contact: Cisse W. Spragins **Phone:** (608) 241-0202

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

5408154 161/34

5417401 161/12

Ms. Victoria Dunnum
Bell Laboratories, Inc.
3699 Kinsman Boulevard
Madison, WI 53704

AUG 05 1992

Dear Ms. Dunnum:

Subject: Liqua-Tox II
EPA File Symbol 12455-AR
Your Letters Dated November 19, 1991 and May 5, 1992

The Agency has reviewed the submissions referred to above and has the following comments:

1. The MRID Numbers cited in your letter of November 19, 1991, are acceptable for supporting the Acute Toxicology requirements for this product.

2. The labeling cannot be accepted until the following revisions are made:

   a. Because you will be changing the container for this product, the Mixing Directions will need to be changed appropriately. On July 22, 1992, Cisse Spragins telephoned Bill Erickson of my staff to inform us that Bell Labs agreed with our request that this product be contained in a plastic bottle rather than a plastic pouch.

   b. Based on our review of the cited Acute Toxicology data, the "PRECAUTIONARY STATEMENTS" section must be revised to read

"PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION: Keep away from humans, domestic animals and pets. If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. Exposure during pregnancy should be avoided. Avoid contact with skin, eyes, or clothing.

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Call a physician or Poison Control Center immediately. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

SYMBOL							
SURNAME							
DATE							

EPA Form 1320-1A (1/90) *Printed on Recycled Paper* OFFICIAL FILE COPY

*U.S. Government Printing Office: 1992 — [illegible]

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

IF ON SKIN: Wash with plenty of soap and water

NOTE TO PHYSICIAN: If ingested, administer Vitamin K_1 intramuscularly or orally as indicated in bishydroxycoumarin overdoses. Repeat as necessary based on monitoring of prothrombin times.

ENVIRONMENTAL HAZARDS

Keep out of lakes, streams, or ponds. Do not contaminate water by cleaning of equipment or disposal of wastes."

c. If the container is changed from a pouch to a plastic bottle, the "CONTAINER DISPOSAL" statement must be changed to read

"CONTAINER DISPOSAL: Do not reuse empty container. Rinse bottle thoroughly. Then securely wrap empty bottle in newspaper and discard in trash."

3. Please note that an outer carton label must be submitted if this product is to be sold with an outer package.

Sincerely yours,

RAF

Robert A. Forrest
Product Manager (14)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

08/04/92:ERICKSON:DISK4:12455-AR.LBL

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol 12455-AR / Liqua Tox II

TO: Robert Forrest PM 14
Insecticide-Rodenticide Branch
Registration Division (H7505C)

FROM: Ian Blackwell Ian Blackwell 3/12/92
Precautionary Review Section E 3/17/92
Registration Support Branch
Registration Division (H7505C)

APPLICANT: Bell Laboratories, Inc.
3699 Kinsman Boulevard
Madison, Wisconsin 53704

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Sodium Salt of Diphacinone--2-Diphenylacetyl-1,3-indandione	0.106
Inert Ingredients:	99.894
Total	100.0%

2

BACKGROUND: The registrant, Bell Laboratories, requests that Liqua Tox II be registered using acute toxicity data gathered using DITRAC Tracking Powder (12455-56) due to similar percentages of active ingredient in the two products. The registant did not request registration based on substantially similar formulation, but based on previous dealings they have had with other products which were batched under Registration Eligibility Documents (REDs) for the active ingredient warfarin. The acute toxicity data for Ditrac was reviewed by Donna Williams 8/13/86. The MRID numbers of the acute toxicity data for the Ditrac Tracking Powder are 00158434, 00158436 through 00158440, 00158438 and 00164171.

RECOMMENDATIONS: RSB/PRS findings are:

The acute toxicity data of Ditrac Powder cannot be used to support Liqua Tox II solely on the basis of similarity of percentages of active ingredient or batching of other active ingredients. However, from an acute toxicological standpoint, data generated using Ditrac Tracking Powder may be used to support Liqua Tox II based on substantially similar formulas.

LABELING:

1. The precautionary statements under Hazard to Humans and Domestic Animals should be revised to:

   "Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling."

2. The statements of practical treatment should be revised to:

   "<u>If in eyes</u>: Flush eyes with plenty of water. Call a physician if irritation persists."

   Both products should display the following statement:

   "<u>If on skin</u>: Wash with plenty of soap and water. Get medical attention."

3. The following labeling was obtained from Ditrac Tracking Powder. It is not supported by the acute toxicity data, but is suggested because it was found to be applicable to Ditrac. The PM Team should decide whether alternative labeling language would better represent the hazards posed by Liqua Tox II.

   "This product can be absorbed through the skin, so it should be handled with gloves. Keep away from humans, domestic animals or pets. This material may reduce the clotting ability of the blood and cause bleeding. Exposure during pregnancy should be avoided. Do not contaminate feed or foodstuffs."

3

"If swallowed: Call a physician or Poison Control Center immediately."

"Note To Physician: If ingested, administer Vitamin K_1 intramuscularly or orally as indicated in bishydroxycoumarin overdoses. Repeat as necessary based on monitoring of prothrombin times."

4. As Ditrac Tracking Powder and other anticoaggulant rodenticides are classified as restricted use pesticides, the PM Team should decide whether this product should also be classified as a restricted use pesticide or if alternative labeling language is sufficient to offset the hazard posed by this product.

Bell Laboratories, Inc.
3699 Kinsman Boulevard, Madison, Wisconsin 53704 U.S.A. / 608/241-0202 / Fax: 608/241-9631

May 5, 1992

FEDERAL EXPRESS
2028124663

Mr. Robert A. Forrest
Product Manager (14)
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division-(H7505C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: L1QUA-TOX II
EPA File Symbol: 12455-AR

Dear Mr. Forrest:

Enclosed for your review please find five (5) copies of new proposed labeling for the above mentioned product. Please disregard the proposed labeling previously submitted.

We have revised the labeling to be consistent with the Warfarin R.E.D., as well as our several recently approved products. (ie. to contain the new directions for use paragraphs.)

We look forward to your review of our labeling, as well as our Product Specific Chemistry Data submitted on January 2, 1992.

If you should have any questions, please contact us. Thank you for your time and consideration.

Sincerely,

Bell Laboratories, Inc.

Victoria J. Dunnum

Victoria J. Dunnum
Registration Specialist

VJD:pml

Enclosures

Liqua-Tox II

Mix contents of pouch with 1 quart of water.

ACTIVE INGREDIENT:	
Sodium Salt of Diphacinone; (2-Diphenylacetyl-1,3-indandione). ...	0.106%
INERT INGREDIENTS	99.894%
TOTAL	100.000%

KEEP OUT OF REACH OF CHILDREN
CAUTION

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help to prevent accidents:

1. Store product not in use in a location out of reach of children and pets.
2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations equipped for dispensing fiquid rodenticide baits. These stations must be resistant to destruction by dogs and by children under six years of age, and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hooled livestock, raccoons, bears, or other potentially destructive animals, or in areas prone to vandalism.
3. Dispose of product container and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS: This product may be used to control Norway rats (Rattus norvegicus), roof rats (R. rattus), and house mice (Mus musculus) in homes; in industrial, agricultural, and commercial buildings; and in similar manmade structures. Do not use LIQUA-TOX II in any area where there is a possibility of contaminating food or surfaces that come in direct contact with food.
MIXING DIRECTIONS: Thoroughly mix contents of one 1.68 fl. oz. package in 1 quart (32 fluid ounces) of water.
SELECTION OF TREATMENT AREAS: Determine areas where rats and mice will most likely find and consume bait. Generally, these areas are along walls, by gnawed openings, beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or their signs have been seen.

APPLICATION DIRECTIONS

RATS: Provide a minimum of 1 pint (16 fluid ounces) of LIQUA-TOX II in each dispenser (suitably-equipped bait station, chick fount, or other suitable device). If infested area is large, or if rat population appears to be high, use dispensers at several locations. Space dispensers and refill them as needed to ensure that bait is exposed in all infested areas where it can be used without putting nontarget organisms at risk.
MICE: Provide 1/2-pint (8 fluid ounces) placements of LIQUA-TOX II in suitably-equipped bait stations, chick founts, or other appropriate vessels. Place dispensers at intervals of 8-12 feet in all infested areas where bait can be used without putting nontarget organisms at risk.
RATS & MICE: Replace contaminated or spoiled bait immediately. Collect and properly dispose of dead animals and bait that is no longer needed. Continue treatments as long as target species are being controlled by bait and nontarget species are not at risk.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS
CAUTION

Keep away from humans, domestic animals and pets. Do not expose bait where humans, livestock, poultry, pets, or wildlife can drink it. Do not contaminate water by cleaning of equipment or disposal of wastes. Apply this product only as specified on this label.

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If swallowed by humans, domestic animals, or pets, this material may reduce the clotting ability of the blood and cause bleeding. In such case intramuscular and oral administrations of Vitamin K_1 combined with blood transfusions are indicated as in the case of hemorrhage caused by overdoses of bishydroxycoumarin.

ENVIRONMENTAL HAZARDS

Keep out of lakes, streams, or ponds.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.
STORAGE: Store only in original container, in a dry place inaccessible to children and pets.
PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.
CONTAINER DISPOSAL: Securely wrap original container in several layers of newspaper and discard in trash.

EPA Est. No. 12455-WI-1 EPA Reg. No. 12455-61

NET CONTENTS: 1.68 Fl. Oz. (49.68 ml)

Mfg. by:

Bell Laboratories, Inc.
Madison, WI 53704 U.S.A.

Bell Laboratories, Inc.
3699 Kinsman Boulevard, Madison, Wisconsin 53704 U.S.A. / 608/241-0202 / Fax: 608/241-9631

November 19, 1991

FEDERAL EXPRESS
792255721 5

Mr. Robert A. Forrest
Product Manager (14)
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division-(H7505C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: LIQUA-TOX II
EPA File Symbol: 12455-AR
Your Letters Dated Oct. 24 and Oct. 28, 1991

Dear Mr. Forrest:

Thank you for your review of our Product Chemistry data submitted August 13, 1991. The following is our response to your comments received in the October 24, 1991 letter.

1. In reference to the CSF:

   a. With regard to your request for the registration number for Sodium Diphacinone Technical, the only registration for a product containing Sodium Diphacinone is EPA Reg. No. 3240-17 which is a water soluble concentrate at 0.106%. Sodium Diphacinone Technical is not registered, as it is not sold as a technical-grade product. As it is used in pesticide products, however, generic data are required through the EPA Reregistration process currently underway. In response to Phase 2 of the reregistration process for Sodium Diphacinone, Chemical No: 67705, the complete Product Chemistry package for Sodium Diphacinone technical was submitted by our sister company, Motomco Ltd. in August 1990. This submission was assigned MRID numbers: 41613401 and 41613402 and contained the full manufacturing procedure, impurity analysis, etc., for Sodium Diphacinone Technical.

When EPA reviewed the data, they advised us to resubmit the package as we had mistakenly marked some pages as "confidential" which were not allowed to be. We resubmitted the data with the corrections in December, 1990. This submission was assigned new MRID numbers: 41727801, 41727802, and 41727803. These studies should contain all the necessary chemistry information for Sodium Diphacinone Technical.

b. We have made the appropriate corrections to ensure that our CSF and product chemistry data are consistent.

Enclosed please find a CSF dated 10-31-91, which supercedes the CSF dated 5/1/90, as well as three (3) copies of each corrected page to be included in the Product Chemistry volumes. These pages include:

Volume 2:	Page 2 of 17
	Page 4 of 17
Volume 3:	Page 4 of 49

c. We have provided the identical pH value which is in the chemistry data on the revised CSF.

d. We have provided the identical density value which is in the chemistry data on the revised CSF.

2. We have provided the mixing time and temperature within Guideline 61-2(b) as required by the Pesticide Assessment Guidelines. Enclosed please find three (3) copies of a revised Page 6 of 17 to be incorporated within Volume 2.

3. We have included three (3) copies of the revised page 5 of 33 of Volume 4, which reflects that the storage stability study, Guideline 63-17, is in progress. However, for your information only, (not to be included in the Product Chemistry volumes) we have enclosed a progress report of the study. The study completion date is June 1992.

Regarding your letter of October 28, 1991, please be advised that we wish to cite the following MRID Numbers in order to fulfill the toxicological data requirements:

			MRID #
81-1	Acute oral toxicity	- Rat	000158434
81-2	Acute dermal toxicity	- Rabbit/Rat	00158439
81-3	Acute inhalation toxicity	- Rat	00158440
81-4	Primary eye irritation	- Rabbit	00158438
81-5	Primary dermal irritation		00158437 & 00164171
81-6	Dermal sensitization		00158436

These studies were conducted on DITRAC Tracking Powder, EPA Reg. No. 12455-56, which contains 0.2% Diphacinone. EPA provided groupings of Warfarin products which were considered similar for the purposes of Acute Toxicity testing in the Warfarin R.E.D. (please see attached copy). Group 2 contains (among other things) EPA Reg. No. 655-443 - Prentiss' Tracking Powder (1.0% Warfarin) as well as EPA Reg. No. 12455-22 - Bell's LIQUA-TOX (0.54% Warfarin, Sodium Salt). Therefore, Acute Toxicity data on one of these products will suffice for both. Given this grouping, we feel it is reasonable to cite Acute Toxicity studies conducted on DITRAC Tracking Powder (0.2% Diphacinone) as applicable to LIQUA-TOX II (0.106% Diphacinone, Sodium Salt).

Lastly, the Agency questioned the similarity of LIQUA-TOX II to Motomco Water Soluble Rodenticide Concentrate (EPA Registration No. 3240-17). Please be advised that the CSF dated 7-24-73 for 3240-17 is correct. The product contains 0.106% Diphacinone, Sodium Salt. LIQUA-TOX II also contains 0.106% Diphacinone, Sodium Salt. Both products are then diluted in water by the same proportion to obtain the liquid bait.

If you should have further concerns, please contact us. We look forward to a favorable review.

Sincerely,

Bell Laboratories, Inc.

Cisse W. Sprgains
Manager of Research & Development

CWS:pml
Enclosures

Liqua-Tox II

Mix contents of pouch with 1 quart of water.

ACTIVE INGREDIENT:

Sodium Salt of Diphacinone — 2-Diphenylacetyl-1,3-indandione.	0.106%
INERT INGREDIENTS	99.894%
TOTAL	100.00%

CAUTION
KEEP OUT OF REACH OF CHILDREN
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION

Keep away fom children, pets, and domestic animals and wildlife. Do not expose bait where humans, livestock, poultry, pets, or wildlife can drink it. Treated baits should be placed in locations not accessible to children, pets, wildlife, domestic animals, or in tamper-proof bait boxes. Do not contaminate water by cleaning of equipment or disposal of wastes. Apply this product only as specified on this label.

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If swallowed by humans, domestic animals, or pets, this material may reduce the clotting ability of the blood and cause bleeding. In such case intramuscular and oral administrations of Vitamin K1 combined with blood transfusions are indicated as in the case of hemorrhage caused by overdoses of bishydroxycoumarin.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS: This product may be used to control Norway rats (Rattus norvegicus), roof rats (R. rattus), and house mice (Mus musculus) in homes; in industrial, agricultural, and commercial buildings; and in similar manmade structures. Place LIQUA-TOX II in locations not accessible to children, pets, domestic animals, and nontarget wildlife, or in secured, tamper-proof bait stations equipped for dispensing liquid rodenticide baits. Do not use LIQUA-TOX II in any area where there is a possibility of contaminating food or surfaces that come in direct contact with food.

MIXING DIRECTIONS: Thoroughly mix contents of one 1.68 fl. oz. package in 1 quart (32 fluid ounces) of water.

SELECTION OF TREATMENT AREAS: Determine areas where rats and mice will most likely find and consume bait. Generally, these areas are along walls, by gnawed openings, beside burrows, in corners and concealed places, between floors and walls, or in other locations where signs of rats and mice have been seen.

APPLICATION DIRECTIONS:

Norway and Roof Rat: Provide a minimum of 1 pint (16 fluid ounces) of LIQUA-TOX II in each dispenser (suitably-equipped bait station, chick fount, or other suitable device). If infested area is large, or if rat population appears to be high, use dispensers at several locations. Space dispensers and refill them as needed to ensure that bait is exposed in all infested areas where it can be used without putting nontarget organisms at risk.

House mice: Provide 1/2-pint (8 fluid ounces) placements of LIQUA-TOX II in suitably-equipped bait stations, chick founts, or other appropriate vessels. Place dispensers at intervals of 8-12 feet in all infested areas where bait can be used without putting nontarget organisms at risk.

Additional Directions for Rats and Mice: Replace contaminated or spoiled bait immediately. Collect and properly dispose of dead animals and bait that is no longer needed. Continue treatments as long as target species are being controlled by bait and nontarget species are not at risk.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

STORAGE: Store only in original container, in a dry place inaccessible to children and pets.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Securely wrap original container in several layers of newspaper and discard in trash.

EPA Est. No. 12455-WI-1 EPA Reg. No. 12455-AQ

NET CONTENTS: 1.68 Fl. Oz. (49.68 mL)

Bell Laboratories, Inc.
3699 Kinsman Boulevard, Madison, Wisconsin 53704

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: Screening of Audit of Bell Laboratories, Inc., Conducted on June 4, 1991

FROM: William W. Jacobs
Insecticide-Rodenticide Branch
Registration Division (H7505C)

TO: Owen F. Beeder
Laboratory Audit Coordinator
Registration Support Branch
Registration Division (H7505C)

I have examined the materials attached to your memorandum of April 10, 1992, which pertained to the most recent laboratory audit of Bell Laboratories, Inc. I have concluded that there is no need for a formal detailed review of the audit report as far as the laboratory efficacy studies audited are concerned.

The audit of June 4, 1991, was at least EPA's third lab audit of Bell Laboratories but the first since EPA began to require that efficacy studies be run according to "Good Laboratory Practices" (GLPs). Comparing the most recent audit with the synopses provided for the two prior audits suggests that substantial improvements have been made to the facility and in the conduct of laboratory efficacy studies. The quality of Bell's data submissions has improved greatly over the past year. Some improvements (e.g., in data transcription, reporting information for control-group animals) have been apparent in Bell's efficacy data reports submitted since the audit of June 4, 1991. If inspectors had other reasons to be in Madison, WI, they could visit Bell briefly to make sure that the facilities themselves have been improved.

Of the laboratory efficacy studies audited, four (the studies assigned MRID Nos. 416414-01, 416414-02, 416744-01, and 416744-02) have been replaced by newer studies. The studies assigned MRID Nos. 416490-01 and 416490-02 were not accepted as originally submitted but were accepted subsequently after Bell provided additional documentation that EPA requested. I cannot justify further review of the audits of these studies, four of which have been rendered obsolete and two of which two have been upgraded.

The inspectors report that Bell tested baits containing more than one active ingredient in the same room and that Bell placed newly acquired animals in the same room where tests were being run. I believe that the first of these practices is appropriate for the types of studies being run but find that failure to quarantine new animals is inexcusable.

The laboratory efficacy tests audited involved bait formulations prepared with low concentrations of non-volatile toxicants. I see no reason for EPA to insist that products such as these, if they contain different active ingredients, must be tested in separate rooms. For volatile materials, such a requirement is appropriate. With volatiles, control-group subjects also would have to be housed separately from toxicant-exposed subjects. The only likely problems with testing baits containing two different active ingredients in one room would result from sloppy lab work. Running tests in separate rooms would not prevent confounding of studies if personnel were careless or incompetent.

The problems with placing newly acquired animals ("incoming test systems" in GLP parlance) in the same room with animals being used in tests are that the new animals might vector diseases or parasites into the facility and that the presence of such agents would alter the test results. The potential impact of additional sources of mortality on laboratory efficacy tests of rodenticide baits would be the overrating of bait effectiveness.

As a check against confounding sources of mortality in the laboratory, EPA's protocols for performance of rodenticide baits require use of a control group kept under the same conditions as the test group but not exposed to the toxic bait. If there are more than two mortalities in the control group, the test is invalidated. (Bell has reported deaths among control-group animals in at least one laboratory efficacy study.)

Because the effects of diseases or parasites could interact synergistically with those of the bait, newly acquired animals must be quarantined as an added precaution to reduce the likelihood that test group animals would die from causes other than those directly associated with the bait under study. Quarantining also would seem to be in the laboratory's own best interests, as the presence of disease can lead to complete shutdown a facility and invalidation of all of its recent animal research.

422076-ØØ

TRANSMITTAL DOCUMENT:

NAME AND ADDRESS OF SUBMITTER:

Bell Laboratories, Inc.
3699 Kinsman Blvd.
Madison, WI 53704

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED:

40 CFR §158.150 - 190 Product Chemistry
Liqua-Tox II EPA File Symbol: 12455-AR

TRANSMITTAL DATE:

January 2, 1992

LIST OF SUBMITTED STUDIES:

Volume 1: Administrative Materials

Volume 2: 42076Ø1
To replace MRID # 41996601

61 Series
61-1(a) Product Identity
61-1(b) Statement of Formula and Product Composition
61-2(a) Description of Beginning Materials
61-2(b) Manufacturing Process
61-3 Discussion of Formation of Impurities
Appendix I

Volume 3: 42076Ø2
To replace MRID # 41996602

62 Series
62-1 Preliminary Analysis
62-2 Certified Limits
62-3 Analytical Method
Appendix II

Volume 4: 42157401
To replace MRID # 41996603

63 Series
63-2 Color
63-3 Physical State
63-4 Odor
63-7 Density
63-12 pH
63-14 Oxidizing/Reducing
63-15 Flammability
63-16 Explodability
63-17 Storage Stability
63-18 Viscosity
63-19 Miscibility
63-20 Corrosion Charact.
63-21 Dielectric Voltage
Appendix III

Company Official: Victoria J. Dunnum 1-2-92
Victoria J. Dunnum - Registration Specialist
Company Name: Bell Laboratories, Inc.
Company Contact: Cisse W. Spragins **Phone:** (608) 241-0202

Bell Laboratories, Inc. 3699 Kinsman Blvd. • Madison, WI 53704 • 608/241-0202 • Fax: 608/241-9631

Bell Laboratories, Inc.
3699 Kinsman Boulevard, Madison, Wisconsin 53704 U.S.A. / 608/241-0202 / Fax: 608/241-9631

5411766

161/37

February 10, 1992

FEDERAL EXPRESS
7922557694

Mr. Robert A. Forrest
Product Manager (14)
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division-(H7505C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: LIQUA-TOX II
EPA File Symbol: 12455-AR
Your Letter Dated February 5, 1992

Dear Mr. Forrest:

Enclosed per your request please find three (3) copies of the missing page in Volume 2, page 5 of 5.

Please include it in the Volume and assign a MRID#. Again, we are sorry if this misunderstanding has caused any inconveniences. We look forward to hearing from you regarding this matter.

Sincerely,

Bell Laboratories, Inc.

Victoria J. Dunnum

Victoria J. Dunnum
Registration Specialist

VJD/ajb

Enclosures

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

5410867 161/38

Ms. Victoria Dunnum
Bell Laboratories, Inc.
3699 Kinsman Boulevard
Madison, WI 53704

FEB 5 1992

Dear Ms. Dunnum:

Subject: Liqua-Tox II
EPA File Symbol 12455-AR
Your Submission Dated January 31, 1992

The Agency has reviewed your submission and has the following comments:

1. With the submission of page 17 that previously was missing, Product Chemistry volume 3 is complete.

2. Product Chemistry volume 2 is still incomplete. The page 5 that is missing is page 5 of 5 in the front of the volume, rather than the page 5 of 17 that you submitted from the data section. Our previous letter may not have clearly indicated which page 5 was missing. Please submit three (3) copies of this missing page. We will include them in the volume and assign MRID numbers for the completed volumes.

Contact William Erickson at 703-305-5408 or 305-6600 if you have any questions about this letter.

Sincerely yours,

Robert A. Forrest
Product Manager (14)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

2/04/92:ERICKSON:DISK 4:12455-AR.RJ2

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

EPA Form 1320-1 (12-70) *U.S.GPO:1989-624-485/10186 OFFICIAL FILE COPY

Bell Laboratories, Inc.
3699 Kinsman Boulevard, Madison, Wisconsin 53704 U.S.A. / 608/241-0202 / Fax: 608/241-9631

January 31, 1992

FEDERAL EXPRESS
7922557871

Mr. Robert A. Forrest
Product Manager (14)
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division-(H7505C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: LIQUA-TOX II
EPA File Symbol: 12455-AR
Your Letter Dated January 21, 1992

Dear Mr. Forrest:

Enclosed per your request, please find three (3) copies of each of the following pages, which were apparently missing in our submission dated January 2, 1992:

VOLUME 2 - Page 5

VOLUME 3 - Page 17

Please attach them to the volumes and assign an MRID # for the completed volumes.

We are sorry if this has caused you any inconveniences. If you should have any questions regarding this matter, please do not hesitate to contact us. We look forward to your review.

Sincerely,

Bell Laboratories, Inc.

Victoria J. Dunnum

Victoria J. Dunnum
Registration Specialist

VJD:pml

Enclosures

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 2 1 1992

5409792 161/11

Ms. Victoria Dunnum
Bell Laboratories, Inc.
3699 Kinsman Boulevard
Madison, WI 53704

Dear Ms. Dunnum:

Subject: Liqua-Tox II
EPA File Symbol 12455-AR
Your Submission Dated January 2, 1992

The Agency has reviewed your submission and has the following comments:

1. The progress report for Product Chemistry guidelines 63-17 (Storage Stability) and 63-20 (Corrosion Characteristics) has been placed in the file for this product. Submit the entire studies when completed.

2. The revised Product Chemistry volumes, containing the corrected pages previously submitted alone, cannot be accepted until you correct the following deficiencies:

   a. Judging from the pagination of Volume 2, page 5 was omitted.

   b. Judging from the pagination of Volume 3, page 17 was omitted.

   Submit three (3) copies of each missing page. We will attach them to the volumes and assign MRID numbers for the completed volumes.

3. The Acute Toxicology studies cited in your letter of November 19, 1991, are presently being reviewed to determine if they satisfy the data requirements for this product.

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

EPA Form 1320-1 (12-70) *U.S.GPO:1989-624-485/10186 OFFICIAL FILE COPY

Contact William Erickson at 703-305-5408 or 305-6600 if you have any questions about this letter.

Sincerely yours,

Robert A. Forrest
Product Manager (14)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Enclosure: Report of Analysis for Compliance with PR Notice 86-5

1/16/91:ERICKSON:DISK 4:12455-AR.REJ

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

BELL LABORATORIES
3699 KINSMAN BLVD.
MADISON, WI 53704

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 01/07/92. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents. If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below. These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels. The rejected studies and their deficiencies are described below.

Rejected study [02] :

* Judging from the pagination of the study, pages/....5..... ~~were~~ was omitted from the submitted copy.

Rejected study [03] :

* Judging from the pagination of the study, pages/....17..... ~~were~~ was omitted from the submitted copy.

421574-00

TRANSMITTAL DOCUMENT:

NAME AND ADDRESS OF SUBMITTER:

Bell Laboratories, Inc.
3699 Kinsman Blvd.
Madison, WI 53704

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED:

40 CFR §158.150 - 190 Product Chemistry
Liqua-Tox II EPA File Symbol: 12455-AR

TRANSMITTAL DATE:

January 2, 1992

LIST OF SUBMITTED STUDIES:

Volume 1: Administrative Materials

Volume 2: 61 Series
61-1(a) Product Identity
To replace MRID # 41996601
61-1(b) Statement of Formula and Product Composition
61-2(a) Description of Beginning Materials
61-2(b) Manufacturing Process
REJECTED (02)
61-3 Discussion of Formation of Impurities
Appendix I

Volume 3: 62 Series
REJECTED (03)
62-1 Preliminary Analysis
To replace MRID # 41996602
62-2 Certified Limits
62-3 Analytical Method
Appendix II

Volume 4: 63 Series
42157401
To replace MRID # 41996603

63-2 Color
63-3 Physical State
63-4 Odor
63-7 Density
63-12 pH
63-14 Oxidizing/Reducing
63-15 Flammability
63-16 Explodability
63-17 Storage Stability
63-18 Viscosity
63-19 Miscibility
63-20 Corrosion Charact.
63-21 Dielectric Voltage
Appendix III

Company Official: Victoria J. Dunnum 1-2-92
Victoria J. Dunnum - Registration Specialist
Company Name: Bell Laboratories, Inc.
Company Contact: Cisse W. Spragins **Phone:** (608) 241-0202

Bell Laboratories, Inc.
3699 Kinsman Boulevard, Madison, Wisconsin 53704 U.S.A. / 608/241-0202 / Fax: 608/241-9631

January 2, 1992

FEDERAL EXPRESS
7922557506

Mr. Robert A. Forrest
Product Manager (14)
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division-(H7505C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: LIQUA-TOX II
EPA File Symbol: 12455-AR
Your Letter Dated December 11, 1991
Our Letter Dated November 19, 1991

Dear Mr. Forrest:

Enclosed as requested, please find three (3) copies of the revised Product Chemistry volumes. These volumes, which were assigned MRID #'s 419966-01, 419966-02, and 419966-03 for Volumes 2, 3, and 4, respectively, now include the corrected pages. As you may recall, "replacement pages" were originally enclosed within our November 19, 1991 letter.

As discussed in our previous letter, only the following pages have had changes from the last submission:

Volume 2: Page 2 of 17, Page 4 of 17, Page 6 of 17

Volume 3: Page 4 of 49

Volume 4: Page 5 of 33

The changes made in Volume 2 and 3 were made to ensure that our Product Chemistry Data was consistent with our CSF, as well as the addition of the mixing time and temperature for Guideline 61-2(b). Volume 4's change reflected the status of the Storage Stability study.

Lastly, we have once again included, in Volume 1, a "Progress Report for Storage Stability and Corrosion Characteristics", as well as a copy of a single page within the Warfarin R.E.D. These two pages were mistakenly returned to us with the "replacement pages". They are enclosures to our November 19, 1991 letter and should be reviewed by the Agency. They are not part of the Product Chemistry.

Thank you for your cooperation in this matter. If you should have any questions, please do not hesitate to contact us.

Sincerely,

Bell Laboratories, Inc.

Victoria J. Dunnum

Victoria J. Dunnum
Registration Specialist

VJD:pml

Enclosures

421574-00

TRANSMITTAL DOCUMENT:

NAME AND ADDRESS OF SUBMITTER:

Bell Laboratories, Inc.
3699 Kinsman Blvd.
Madison, WI 53704

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED:

40 CFR §158.150 - 190 Product Chemistry
Liqua-Tox II EPA File Symbol: 12455-AR

TRANSMITTAL DATE:

January 2, 1992

LIST OF SUBMITTED STUDIES:

Volume 1:	Administrative Materials	
Volume 2:	61 Series	
	61-1(a) Product Identity	
To replace	61-1(b) Statement of Formula and Product Composition	
MRID #	61-2(a) Description of Beginning Materials	
41996601	61-2(b) Manufacturing Process	
REJECTED (02)	61-3 Discussion of Formation of Impurities	
	Appendix I	
Volume 3:	62 Series	
Rejected (03)	62-1 Preliminary Analysis	
To replace	62-2 Certified Limits	
MRID #	62-3 Analytical Method	
41996602	Appendix II	
Volume 4:	63 Series	
42157407	63-2 Color	63-16 Explodability
To replace	63-3 Physical State	63-17 Storage Stability
MRID #	63-4 Odor	63-18 Viscosity
41996603	63-7 Density	63-19 Miscibility
	63-12 pH	63-20 Corrosion Charact.
	63-14 Oxidizing/Reducing	63-21 Dielectric Voltage
	63-15 Flammability	Appendix III

Company Official: Victoria J. Dunnum 1-2-92
Victoria J. Dunnum - Registration Specialist

Company Name: Bell Laboratories, Inc.
Company Contact: Cisse W. Spragins **Phone:** (608) 241-0202

PROGRESS REPORT FOR STORAGE STABILITY AND CORROSION CHARACTERISTICS

(Guideline Numbers 63-17 and 63-20)

LIQUA-TOX II
EPA File Symbol: 12455-AR

Batch # CL232

Time	Purity
0	0.119%
1 month	0.117%
2 months	0.122%
4 months	0.108%

- Study is in progress.

- Study completion date is June 1992.

- The SOP for this study may be found in the original data packet submitted on July 23, 1991. (MRID # 419966-03).
(and in packet submitted Jan 2, 1992

Bell Laboratories, Inc. 3699 Kinsman Blvd. • Madison, WI 53704 • 608/241-0202 • Fax: 608/241-9631

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DEC 11 1991

5408155 161/11

Ms. Cisse Spragins
Bell Laboratories, Inc.
3699 Kinsman Boulevard
Madison, WI 53704

Dear Ms. Spragins:

Subject: Liqua-Tox II
EPA File Symbol 12455-AR
Your Letter Dated November 19, 1991

Enclosed are the corrected pages you submitted to be included in the Product Chemistry volumes for this pending product. It is not acceptable to send in only relacement pages for a study previously submitted, because that study has already received an MRID number and been microfilmed. Please comply with the instructions on the sheet attached to this letter when resubmitting the corrected information.

We assume from your letter that you wish to continue with the Selective Method of support for this product. We are presently reviewing the MRID numbers you cited to satisfy the Acute Toxicology data requirements.

Pursuant to 40 CFR § 152.105, if the above requested information or a written request for additional time is not submitted to the Registration Division within 75 days of receipt of this notice, the application will be administratively withdrawn. In that event, any subsequent submission relating to the same product must be submitted as a new application.

Contact William Erickson at (703) 305-5408 or 305-6600 if you have any questions about this letter.

Sincerely yours,

Robert A. Forrest
Product Manager (14)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Enclosure

12/11/91:ERICKSON:DISK 4:12[illegible] CONCURRENCES

SYMBOL								
SURNAME								
DATE								

EPA Form 1320-1 (12-70) *U.S.GPO:1989-624-485/10186 OFFICIAL FILE COPY

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

BELL LABORATORIES
3699 KINSMAN BLVD.
MADISON, WI 53704

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 11/26/91. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

Rejected study [01] :

It is not acceptable to send in only replacement pages or inadvertently omitted pages for a study previously submitted. A complete replacement version of the study, which meets all of the requirements of PR Notice 86-5, should be submitted. On the title page of the replacement study, identify the previously submitted study by EPA accession or MRID number. If these EPA numbers are unknown to you, call EPA at (703) 557-3240 for assistance in identifying the appropriate number(s). In the transmittal of the replacement study, explain fully both the relationship of the newly submitted replacement study to the original study, and the specific differences between the two versions. This will allow our reviewers to tell quickly whether or not the resubmission will significantly impact a review already underway or completed.

Bell Laboratories, Inc.
3699 Kinsman Boulevard, Madison, Wisconsin 53704 U.S.A. / 608/241-0202 / Fax: 608/241-9631

November 19, 1991

FEDERAL EXPRESS
792255721 5

Mr. Robert A. Forrest
Product Manager (14)
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division-(H7505C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: LIQUA-TOX II
EPA File Symbol: 12455-AR
Your Letters Dated Oct. 24 and Oct. 28, 1991

Dear Mr. Forrest:

Thank you for your review of our Product Chemistry data submitted August 13, 1991. The following is our response to your comments received in the October 24, 1991 letter.

1. In reference to the CSF:

   a. With regard to your request for the registration number for Sodium Diphacinone Technical, the only registration for a product containing Sodium Diphacinone is EPA Reg. No. 3240-17 which is a water soluble concentrate at 0.106%. Sodium Diphacinone Technical is not registered, as it is not sold as a technical-grade product. As it is used in pesticide products, however, generic data are required through the EPA Reregistration process currently underway. In response to Phase 2 of the reregistration process for Sodium Diphacinone, Chemical No: 67705, the complete Product Chemistry package for Sodium Diphacinone technical was submitted by our sister company, Motomco Ltd. in August 1990. This submission was assigned MRID numbers: 41613401 and 41613402 and contained the full manufacturing procedure, impurity analysis, etc., for Sodium Diphacinone Technical.

Regarding your letter of October 28, 1991, please be advised that we wish to cite the following MRID Numbers in order to fulfill the toxicological data requirements:

			MRID #
81-1	Acute oral toxicity	- Rat	000158434
81-2	Acute dermal toxicity	- Rabbit/Rat	00158439
81-3	Acute inhalation toxicity	- Rat	00158440
81-4	Primary eye irritation	- Rabbit	00158438
81-5	Primary dermal irritation		00158437 & 00164171
81-6	Dermal sensitization		00158436

These studies were conducted on DITRAC Tracking Powder, EPA Reg. No. 12455-56, which contains 0.2% Diphacinone. EPA provided groupings of Warfarin products which were considered similar for the purposes of Acute Toxicity testing in the Warfarin R.E.D. (please see attached copy). Group 2 contains (among other things) EPA Reg. No. 655-443 - Prentiss' Tracking Powder (1.0% Warfarin) as well as EPA Reg. No. 12455-22 - Bell's LIQUA-TOX (0.54% Warfarin, Sodium Salt). Therefore, Acute Toxicity data on one of these products will suffice for both. Given this grouping, we feel it is reasonable to cite Acute Toxicity studies conducted on DITRAC Tracking Powder (0.2% Diphacinone) as applicable to LIQUA-TOX II (0.106% Diphacinone, Sodium Salt).

Lastly, the Agency questioned the similarity of LIQUA-TOX II to Motomco Water Soluble Rodenticide Concentrate (EPA Registration No. 3240-17). Please be advised that the CSF dated 7-24-73 for 3240-17 is correct. The product contains 0.106% Diphacinone, Sodium Salt. LIQUA-TOX II also contains 0.106% Diphacinone, Sodium Salt. Both products are then diluted in water by the same proportion to obtain the liquid bait.

If you should have further concerns, please contact us. We look forward to a favorable review.

Sincerely,

Bell Laboratories, Inc.

Cisse W. Sprgains
Manager of Research & Development

CWS:pml
Enclosures

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 28 1991

5402350 161/10

Ms. Cisse W. Spragins
Bell Laboratories, Inc.
3699 Kinsman Boulevard
Madison, WI 53704

Dear Ms. Spragins:

Subject: Liqua-Tox II
EPA File Symbol 12455-AR
Your Letter Dated September 4, 1991

The Agency has reviewed your comments about the Acute Toxicology studies required for this pending registration, and we have the following comments:

1. The Acute Toxicology tests specified in our letter of August 14, 1991, are required because your company chose the Selective Method of support for this product. In an Agency letter dated June 27, 1990, you were requested to send a Data Matrix and were told that Acute Toxicology data would be required. In your Data Matrix received by the Agency on September 10, 1990, you cited the public literature for Guideline 81-1 and indicated that Guidelines 81-2, 81-3, 81-4, 81-5, and 81-6 were not applicable. As noted in our letter of August 14, 1991, the public literature cited does not fulfill the toxicology data requirements specified in 40 CFR 158.340 and the other toxicology studies are in fact required. If you wish to continue persuing this registration under the Selective Method of support, you must either provide MRID numbers for studies that will fulfill these requirements, or you must submit data.

2. If you wish to change to Cite All Method of support to fulfill the toxicology requirements, you would have to send a new Certification with Respect to Citation of Data form indicating this change of method of support.

3. You contend that this product is toxicologically similar to Motomco Water Soluble Diphacinone Rodenticide Concentrate (EPA Registration No. 3240-17). We are unable to consider these products similar at present, because there seems to be an error in the percent by weight of active ingredient on the Confidential Statement of Formnula (CSF) for 3240-17

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

dated July 24, 1973. If the percent active ingredient is 0.106% as stated on the CSF, then it will be considerably less in solution when diluted one tablespoon concentrate to one quart of water as specified in the DIRECTIONS on the product label. Please clarify. Update the CSF if it is in error.

Sincerely yours,

Robert A. Forrest
Product Manager (14)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

10/28/91:ERICKSON:DISK 1:12455-AR.TX

Bell Laboratories, Inc.
3699 Kinsman Boulevard, Madison, Wisconsin 53704 U.S.A. / 608/241-0202 / Fax: 608/241-9631

September 4, 1991

FEDERAL EXPRESS
7922556644

Mr. Robert A. Forrest
Product Manager (14)
Insecticide-Rodenticide Branch
Registration Division (H7504C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M. Street, S.W.
Washington, D.C. 20460

RE: LIQUA-TOX II
EPA File Symbol: 12455-AR
Your Letter Dated August 14, 1991

Dear Mr. Forrest:

We appreciate your constructive comments regarding our efficacy studies.

Regarding the acute toxicity studies, we would maintain that our product LIQUA-TOX II is toxicologically similar to EPA Registration Number 3240-17, Motomco Water Soluble Diphacinone Rodenticide Concentrate (0.106% Sodium Diphacinone). We also expect that at the time of Phase 5 of Reregistration of Diphacinone, that EPA will provide, in a manner similar to Warfarin, a grouping of products that are deemed similar for the purposes of acute toxicity testing. We would like to then request that EPA grant us at least a conditional registration for LIQUA-TOX II, contingent upon our meeting the acute toxicity requirements which will be set forth at the time of Phase 5 of Reregistration of Diphacinone. We are currently intensively involved in generating the extensive generic data required for the Reregistration of Diphacinone.

We appreciate your time and consideration.

Sincerely,

Bell Laboratories, Inc.

Cisse W. Spragins
Manager of Research & Development

CWS:pml

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 24 1991

5400571 161/10

5401140 161/16

Ms. Victoria Dunnum
Bell Laboratories, Inc.
3699 Kinsman Boulevard
Madison, WI 53704

Dear Ms. Dunnum:

Subject: Liqua-Tox II
EPA File Symbol 12455-AR
Your Letters Dated July 23 and August 13, 1991

The Agency has reviewed the above-mentioned Product Chemistry data and has the following comments:

1. In reference to the Confidential Statement of Formula (CSF):

   a. Provide the Registration No. of the source of the active ingredient.

   b. The upper and lower certified limits on your CSF differ from the data submitted under Guideline 62-2. Please make the appropriate corrections to ensure that your data is consistent.

   c. You provide a pH of 4.3 in your chemistry data, but you state it is N/A on your CSF. Please clarify.

   d. Density of the product is stated as 1.003 g/cc in your chemistry data but listed as N/A on your CSF. Please clarify.

2. In reference to the product specific data requirements, you must specify the mixing time and temperature in the Statement of Composition.

3. Provide the data for the Storage Stability study. Simply stating 'stable' is not acceptable.

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

Pursuant to 40 CFR 152.105, if the above requested information or a written request for additional time is not submitted to the Registration Division within 75 days of receipt of this notice, the application will be administratively withdrawn. In that event, any subsequent submission relating to the same product must be submitted as a new application.

Contact William Erickson at (703) 557-4408 or 557-2600 if you have any questions about this letter.

Sincerely yours,

Robert A. Forrest
Product Manager (14)
Insecticide-Rodenticide Branch
Registration Division (H7504C)

10/24/91:ERICKSON:DISK 1:12455-AR.PC

PRODUCT CHEMISTRY / [illegible]

TO: PM ________ FROM: Reviewer: INDIRA GAIROLA Date: 09/17/91

EPA REG. NO.: 12455-AR. PRODUCT NAME: LIQUA-TOX II

Please provide the requested information for the following checked items:

1. [ ] Submit the product specific product chemistry data for your product. [ ] If submitted earlier, provide MRID Number(s). [ ] Your product is not sufficiently similar to the product you referenced.

2. In reference to the Confidential Statement of Formula (CSF), please provide the following:

   [ ] a) ✓ pH of product or pH at a specified water dilution in your PC data requirement you state pH of 9.43, CSF states as N/A.

   [ ] b) ✓ Provide Density of product. CSF states it as N/A, PC data states it as 1.003 g/cc, please clarify.

   OK [ ] c) ~~Flash~~ Flash point of product.

   [ ] d) Flash point of product with propellent as per item #6(q) or item #5(c).

   [ ] e) Flame extension of product including flashbacks if noted.

   [ ] f) The upper and lower certified limits based on the pure active ingredients rather than the technical or concentrate. ~~Note that the lower limit of the active ingredients must be the same as the label claim in pure active form.~~

   [ ] g) The upper and lower certified limits of the individually added inerts.

   [ ] ✓ h) Provide Reg No. of the source of active ingredient

   [ ] i)

   [ ] j)

IG 09/17/91

3. [ ] ✓ Based on the current CSF dated ~~5/08/90~~ 5/01/90, your product will ~~not~~ meet the label claim for the active ingredient. ~~Please revise the label or the CSF so that the information agrees.~~

Subject to the above corrections/or requirements

The CSF seen is 5/1/90 no new CSF submitted. The certified limits on p 4 of 49 of 62-2 don't correspond with the 5/1/90 CSF. Date should be consistent.

BG 9/23/91

PRODUCT CHEMISTRY REVIEW (cont'd)

4. [ ] Provide the chemical identity of all components, the percentage composition, CAS Registry Number, and Material Safety Data Sheet (two copies) for the following compounds:

1.

2.

3.

4.

5.

The supplier may contact EPA directly referencing the File Symbol or EPA Registration Number in their response. For dyes, provide the color index and CAS Registry Numbers for all components. For perfumes and flavorings, provide for each component in the mixture: the chemical name, CAS Registry Number, and the percentage or range in percentage in the mixture. Certify that flavors are non-food type. The confidential information submitted by the suppliers is kept confidential under FIFRA Section 10.

5. In the proposed labeling, provide the following information:

[ ] a) Update the label Storage and Pesticide and Container Disposal Statements in accordance with [ ] PR Notice 84-1 for non-aerosol containers for houses and institutional uses or [ ] PR Notice 83-3 for all other uses.

[ ] b) Add the heading PHYSICAL OR CHEMICAL HAZARDS to the label and the appropriate statement per 40 CFR 156.10(h)(2)(iii).

[ ] c) Under the heading PHYSICAL OR CHEMICAL HAZARDS, list the product as Extremely Flammable (because your product contains flammable propellents).

[ ] d) Provided that the solvent does not have insecticidal activity, it should be removed from the ingredient statement active ingredient listing and the percentage added to the inert ingredients. If the solvent has insecticidal properties, provide the EPA Registration Number.

[ ] e) Add a footnote to the inert ingredients indicating: Contains petroleum distillates, xylene or xylene-range aromatic solvent.

[ ] f) Since your data matrix does not provide a dielectrical breakdown voltage, you must add the following statement to the Physical or Chemical Hazards heading:

Do not use this product in or on electrical equipment due to the possibility of shock hazard.

PRODUCT CHEMISTRY REVIEW (cont'd)

[ ] g) The terms active ingredient(s) and inert ingredients should be in the same type size, be aligned to the same margin and be equally prominent.

[ ] h)

[ ] i)

6. In reference to the product specific data requirements, provide the following information:

[ ] a) Statement of Composition: A complete description of the manufacturing/formulation process. Describe equipment used, mixing time, temperature, pressure, etc. Specify the underlined under statement of composition

[ ] b) Discussion of Formation of Unintentional Ingredients: A brief description of impurities formed during the manufacturing/formulation process, in packaging or during storage. If you do not expect any impurities during these stages, please so state.

[ ] c) Certification of Limits: Upper and lower limits of each active and individually added inert component. The lower limit for the active ingredients must be the same as the label claim in pure active form. Your confined limits are different than those N/A - stated on CSF - discrepancy, the components are different and they also does not agree with the same. Explain the

[ ] d) Analytical Method: Provide the methods used to analyze for the active ingredients or a full reference for a published method or MRID Number(s).

[ ] e) Color: In common terms.

[ ] f) Physical State: e.g., solid, liquid, pressurized liquid, etc.

[ ] g) Odor: In common terms.

[ ] h) Density: e.g., lbs/gallon for liquids or lbs/cu.ft. for solids. 1.0039 g/cc

[ ] i) pH: Provide pH of product or pH of a specified water dilution. 9.43

[ ] j) Oxidizing or Reducing Action: Note these characteristics, if any.

[ ] k) Explodability: Note these characteristics, if any.

[ ] l) Viscosity: Can be expressed in centipoise or centistokes. 1.013 cs

[ ] m) Miscibility: Note these characteristics if product is an emulsifiable liquid and mixed with oil. N/A

[ ] n) Corrosion Characteristics: This information can be noted during the storage stability study.

[ ] o) Dielectric Breakdown Voltage: For products used near electrical equipment. not to be used

PRODUCT CHEMISTRY REVIEW (cont'd)

[ ] p) ✓ Storage Stability: The formulated product must be analyzed for its active ingredients at time zero and during one year of storage. The storage should be at warehouse conditions of temperature and humidity and stored in the product's commercial package. Note: For the storage stability study, you may not reference the data on source product concentrate you are using to formulate your product.

The word 'Stable' is not acceptable - need data as above

[ ] q) Flammability: Flash point/flame extension. The flash point reported exceeds the one expected for this product. Please check and resubmit. Mixtures marketed under pressure, including those containing hydrocarbons, are subject in their entirety to tests indicated in 40 CFR Section 156.10(h)(2)(iii) of the maxipackage. Note that flash points for pressurized liquids are conveniently measured after collecting the expelled liquid from the container in an open cup chilled with dry ice (Refer to Aerosol Guide, CSMA).

[ ] If any of the items are not applicable, write N.A. and explain reasons as specified under chemistry data requirements footnotes. See 40 CFR Part 158.

7. [ ] The following is the regulatory status of the inert ingredients under 40 CFR 180.1001 for the exemption of the requirement of a tolerance:

8. Additional Comments:

PRODUCT CHEMISTRY REVIEW

TO: PM _____ FROM: Reviewer: INDIRA GAIROLA Date: 09/30/91

EPA REG. NO.: 12455-AR - PRODUCT NAME: LIQUA-TOX II

FOOD USE ( ) INERTS CLEARED: C ( ), D ( ), E ( ) NON FOOD USE ( )
21 CFR PARTS 170-199: ( ) TOXIC INERTS LIST 1( ), 2( )

Please provide the requested information for the following checked items:

1. [ ] Submit the product specific product chemistry data for your product. [ ] If submitted earlier, provide MRID Number(s). [ ] Your product is not sufficiently similar to the product you referenced.

2. In reference to the Confidential Statement of Formula (CSF), please provide the following:

   [ ] a) pH of product or pH at a specified water dilution.

   [ ] b) Density of product.

   [ ] c) Flash point of product.

   [ ] d) Flash point of product with propellent as per item #6(q) or item #5(c).

   [ ] e) Flame extension of product including flashbacks if noted.

   [ ] f) The upper and lower certified limits based on the pure active ingredients rather than the technical or concentrate. Note that the lower limit of the active ingredients must be the same as the label claim in pure active form.

   [ ] g) The upper and lower certified limits of the individually added inerts.

   [ ] h)

   [ ] i)

   [ ] j)

3. [ ] Based on the current CSF dated _____, your product will not meet the label claim for the active ingredient. Please revise the label or the CSF so that the information agrees.

Applicant has submitted additional information on P.C. Series 63. Please refer to p. 3. for details

10/1/91

my comments of 9/23/90 should be addressed to ~~PM~~ registrant

PRODUCT CHEMISTRY REVIEW (cont'd)

4. [ ] Provide the chemical identity of all components, the percentage composition, CAS Registry Number, and Material Safety Data Sheet (two copies) for the following compounds:

1.

2.

3.

4.

5.

The supplier may contact EPA directly referencing the File Symbol or EPA Registration Number in their response. For dyes, provide the color index and CAS Registry Numbers for all components. For perfumes and flavorings, provide for each component in the mixture: the chemical name, CAS Registry Number, and the percentage or range in percentage in the mixture. Certify that flavors are not food type. The confidential information submitted by the suppliers is kept confidential under FIFRA Section 10.

5. In the proposed labeling, provide the following information:

[ ] a) Update the label Storage and Pesticide and Container Disposal Statements in accordance with [ ] PR Notice 84-1 for non-aerosol containers for houses and institutional uses or [ ] PR Notice 83-3 for all other uses.

[ ] b) Add the heading PHYSICAL OR CHEMICAL HAZARDS to the label and the appropriate statement per 40 CFR 156.10(h)(2)(iii).

[ ] c) Under the heading PHYSICAL OR CHEMICAL HAZARDS, list the product as Extremely Flammable (because your product contains flammable propellents).

[ ] d) Provided that the solvent does not have insecticidal activity, it should be removed from the ingredient statement active ingredient listing and the percentage added to the inert ingredients. If the solvent has insecticidal properties, provide the EPA Registration Number.

[ ] e) Add a footnote to the inert ingredients indicating: Contains aromatic petroleum distillates, xylene or xylene-range aromatic solvent.

[ ] f) Since your data matrix does not provide a dielectrical breakdown voltage, you must add the following statement to the Physical or Chemical Hazards heading:

> Do not use this product in or on electrical equipment due to the possibility of shock hazard.

PRODUCT CHEMISTRY REVIEW (cont'd)

[ ] g) The terms active ingredient(s) and inert ingredients should be in the same type size, be aligned to the same margin and be equally prominent.

[ ] h)

[ ] i)

6. In reference to the product specific data requirements, provide the following information:

[ ] a) Statement of Composition: A complete description of the manufacturing/formulation process. Describe equipment used, mixing time, temperature, pressure, etc.

[ ] b) Discussion of Formation of Unintentional Ingredients: A brief description of impurities formed during the manufacturing/formulation process, in packaging or during storage. If you do not expect any impurities during these stages, please so state.

[ ] c) Certification of Limits: Upper and lower limits of each active and individually added inert component. The lower limit for the active ingredients must be the same as the label claim in pure active form.

[ ] d) Analytical Method: Provide the methods used to analyze for the active ingredients or a full reference for a published method or MRID Number(s).

[ ] e) ✓ Color: In common terms.

[ ] f) ✓ Physical State: e.g., solid, liquid, pressurized liquid, etc.

[ ] g) ✓ Odor: In common terms.

[ ] h) ✓ Density: e.g., lbs/gallon for liquids or lbs/cu.ft. for solids.

[ ] i) ✓ pH: Provide pH of product or pH of a specified water dilution.

[ ] j) ✓ Oxidizing or Reducing Action: Note these characteristics, if any.

[ ] k) ✓ Explodability: Note these characteristics, if any.

[ ] l) ✓ Viscosity: Can be expressed in centipoise or centistokes.

The applicant has submitted additional ~~defects~~ information about the above checked items. These are acceptable & shd be placed in files

[ ] m) Miscibility: Note these characteristics if product is an emulsifiable liquid and mixed with oil.

[ ] n) Corrosion Characteristics: This information can be noted during the storage stability study.

[ ] o) ✓ Dielectric Breakdown Voltage: For products used near electrical equipment.

PRODUCT CHEMISTRY REVIEW (cont'd)

[ ] p) Storage Stability: The formulated product must be analyzed for its active ingredients at time zero and during one year of storage. The storage should be at warehouse conditions of temperature and humidity and stored in the product's commercial package. Note: For the storage stability study, you may not reference the data on source product concentrate you are using to formulate your product.

[ ] q) Flammability: Flash point/flame extension. The flash point reported exceeds the one expected for this product. Please check and resubmit. Mixtures marketed under pressure, including those containing hydrocarbons, are subject in their entirety to tests indicated in 40 CFR Section 156.10(h)(2)(iii) of the maxipackage. Note that flash points for pressurized liquids are conveniently measured after collecting the expelled liquid from the container in an open cup chilled with dry ice (Refer to Aerosol Guide, CSMA).

[ ] If any of the items are not applicable, write N.A. and explain reasons as specified under chemistry data requirements footnotes. See 40 CFR Part 158.

7. [ ] The following is the regulatory status of the inert ingredients under 40 CFR 180.1001 for the exemption of the requirement of a tolerance:

8. Additional Comments:

Bell Laboratories, Inc.
3699 Kinsman Boulevard, Madison, Wisconsin 53704 U.S.A. / 608/241-0202 / Fax: 608/241-9631

5401917 16 1/37

August 23, 1991

FEDERAL EXPRESS
7922556320

Team 14

Mr. Bill Erickson
Insecticide-Rodenticide Branch
Registration Division (H7504C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M. Street, S.W.
Washington, D.C. 20460

RE: Our Phone Conversation of August 19, 1991
LIQUA-TOX II
EPA File Symbol: 12455-AR

Dear Mr. Erickson:

Enclosed per your request in our phone conversation noted above, please find a single copy of our product chemistry submission for LIQUA-TOX II.

As you may recall, our original submission was on July 23, 1991. The following MRID numbers were previously assigned:

Volume 2: 41958101
Volume 3: 41958102
Volume 4: 41958103.

Then on August 13, 1991 we submitted several corrected pages for that submission.

As you explained in our phone conversation, you are in need of a single complete, corrected copy for microfiche purposes.

If you should need anything further or have any questions, please do not hesitate to contact us. We are happy to have assisted you in this matter.

Sincerely,

Bell Laboratories, Inc.

Victoria J. Dunnum

Victoria J. Dunnum
Registration Specialist

VJD:pml

Enclosures

Bell Laboratories, Inc.
3699 Kinsman Boulevard, Madison, Wisconsin 53704 U.S.A. / 608/241-0202 / Fax: 608/241-9631

August 13, 1991

FEDERAL EXPRESS # 7922556014

Mr. Robert A. Forrest
Product Manager (14)
Insecticide-Rodenticide Branch
Registration Division (H7504C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M. Street, S.W.
Washington, D.C. 20460

RE: Our Product Chemistry submission dated July 23, 1991
LIQUA-TOX II
EPA File Symbol: 12455-AR

Dear Mr. Forrest:

As you are aware, on July 23, 1991, we submitted three Volumes of Product Chemistry for LIQUA-TOX II. (For your convenience, we have enclosed a copy of the cover letter.)

Since that time we have discovered a few minor errors in our submitted Volumes. Therefore, we have corrected these errors and have enclosed three (3) copies of each corrected page.

Would you please replace the following pages with the enclosed pages.

Volume 2 -	Page 3 of 5
	Page 4 of 17
Volume 3 -	Page 3 of 4
Volume 4 -	Page 3 of 33
	Page 5 of 33

Lastly, in Volume 4, we are in need of your assistance to insert an additional page, page 22a of 33.

Mr. Forrest, we appreciate your assistance in this matter. If you should have any questions, please do not hesitate to contact us.

Sincerely,

Bell Laboratories, Inc.
Victoria J. Dunnum
Victoria J. Dunnum
Registration Specialist

VJD:pml

Enclosures

Bell Laboratories, Inc.
3699 Kinsman Boulevard, Madison, Wisconsin 53704 U.S.A. / 608/241-0202 / Fax: 608/241-9631

July 23, 1991

FEDERAL EXPRESS
7922556224

Mr. Robert A. Forrest
Product Manager (14)
Insecticide-Rodenticide Branch
Registration Division (H7504C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M. Street, S.W.
Washington, D.C. 20460

RE: LIQUA-TOX II
EPA File Symbol: 12455-AR
EPA Letter Dated June 27, 1990
Product Chemistry

Dear Mr. Forrest:

Enclosed as required in the above mentioned letter, please find three copies of Product Chemistry studies in support of our product registration, LIQUA-TOX II, EPA File Symbol: 12455-AR,

The product chemistry studies include:

Volume 2:	61 Series
Volume 3:	62 Series
Volume 4:	63 Series

Volume 1 consists of the Administrative Materials.

If you should have any questions, please do not hesitate to contact us. We look forward to a favorable review.

Sincerely,

Bell Laboratories, Inc.

Victoria J. Dunnum

Victoria J. Dunnum
Registration Specialist

VJD:pml

Enclosures

419966- 00 02

TRANSMITTAL DOCUMENT:

NAME AND ADDRESS OF SUBMITTER:

Bell Laboratories, Inc.
3699 Kinsman Blvd.
Madison, WI 53704

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED:

40 CFR §158.150 - 190 Product Chemistry

TRANSMITTAL DATE:

July 23, 1991

LIST OF SUBMITTED STUDIES:

Volume 1: Administrative Materials

Volume 2: 61 Series
61-1(a) Product Identity
61-1(b) Statement of Formula and Product Composition
61-2(a) Description of Beginning Materials
41996601 61-2(b) Manufacturing Process
61-3 Discussion of Formation of Impurities
Appendix I

Volume 3: 62 Series
62-1 Preliminary Analysis
62-2 Certified Limits
41996602 62-3 Analytical Method
Appendix II

Volume 4: 63 Series

63-2 Color	63-16 Explodability
63-3 Physical State	63-17 Storage Stability
41996603 63-4 Odor	63-18 Viscosity
63-7 Density	63-19 Miscibility
63-12 pH	63-20 Corrosion Charact.
63-14 Oxidizing/Reducing	63-21 Dielectric Voltage
63-15 Flammability	Appendix III

Company Official: Victoria J. Dunnum
Victoria J. Dunnum - Registration Specialist
Company Name: Bell Laboratories, Inc.
Company Contact: Cisse W. Spragins **Phone:** (608) 241-0202

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

5390000 161/38

Ms. Victoria Dunnum
Bell Laboratories, Inc.
3699 Kinsman Boulevard
Madison, WI 53704

AUG 14 1991

Dear Ms. Dunnum:

Subject: Liqua-Tox II
EPA File Symbol 12455-AR
Your Letters Dated December 10, 1990, and January 24, 1991

The Agency has reviewed the above-mentioned submissions and other data in support of this product and has the following comments:

1. With support of the raw data sheets provided with your letter of January 24, 1991, the efficacy studies submitted on October 1, 1990, are acceptable. MRID numbers for these tests are 416490-01 for the house mouse test and 416490-02 for the Norway rat test.

2. We are pleased to learn that your future reports of studies of liquid baits will include diagrams of how food containers, waterers, and shelter areas are arranged in animal enclosures, and that you will make every attempt to provide sufficient numbers of waterers for all study groups. We also expect that all of your efficacy tests will be continued for their scheduled durations even if all test-group animals have died.

   We further expect that you will use single-sex subgroups for all tank tests and that you will report results obtained in these tests for each sex and subgroup as well as for the test group as a whole. Although you caged sexes separately for the rat test run for Liquatox II, you did not distinguish male results from female results in your test report or on your raw data sheets.

3. The public literature and data cited to fulfill toxicology data requirements are unacceptable to

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

support registration of this product. The public literature cited does not fulfill the toxicology data requirements as specified in 40 CFR 158.340. Additionally, the data cited on 12455-25 cannot be used to support 12455-AR as these products are not substantially similar. One indication of this fact is that the signal word for 12455 is "DANGER" with the skull and crossbones, whereas the signal word on the proposed label for 12455-AR is "CAUTION".

Therefore, you must submit the following studies conducted in accordance with the Agency testing guidelines: acute oral, acute dermal, acute inhalation, primary eye irritation, primary skin irritation, and dermal sensitization study.

4. The packaging specifications submitted on December 10, 1990, are currently being reviewed for acceptability.

5. Regarding the labeling for this product, the USE DIRECTIONS were previously accepted by the Agency. The remainder of the labeling will be reviewed after the above-mentioned outstanding data requirements have been fulfilled.

   Please also be aware that if this product is to be sold in lots of 50 (or any other number) in a carton, the carton must also bear a label. This label should correspond to that used for the smaller package except for differences in "net contents" statements.

Persuant to 40 CFR 152.105, if the above requested information, or a written request for additional time is not submitted to the Registration Division within 75 days of receipt of this notice, the application will be administratively withdrawn. In that event, any subsequent submission relating to the same product must be submitted as a new application.

Contact William Erickson at (703) 557-4408 or 557-2600 if you have any questions about this letter.

Sincerely yours,

Robert A. Forrest
Product Manager (14)
Insecticide-Rodenticide Branch
Registration Division (H7504C)

8/13/91:ERICKSON:DISK 1:12455-AR

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

APR 3 1991

MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol 12455-AR
Ligua-Tox II

FROM: Mary L. Waller Mary L. Waller E 4/25/91
Precautionary Review Section
Registration Support Branch
Registration Division (H75-05C)

TO: Marily Mautz, Acting (PM 16)
Insecticide-Rodenticide Branch
Registration Division (H75-05C)

APPLICANT: Bell Laboratories, Inc.
3699 Kinsmen Boulevard
Madison, WI 53704

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Sodium salt of Diphacinone	0.106%
Inert Ingredient(s):	99.894%
Total	100.0%

Printed on Recycled Paper

BACKGROUND: The PM team has requested that PRS review this registration to determine if the data cited is acceptable to support this registration. The registrant has cited public literature on the acute oral toxicity of diphacinone and also the data on their technical diphacinone product (12455-25).

RECOMMENDATION: RSB/PRS finds the public literature and data cited unacceptable to support registration of this product. The public literature cited does not fulfill the toxicology data requirements as specified in 40 CFR 158.340. Additionally, the data cited on 12455-25 cannot be used to support 12455-AR as these products are not substantially similar. One indication of this fact is that the signal word for 12455-25 is "DANGER" with the skull & crossbones and the signal word on the proposed label for 12455-AR is "CAUTION".

Therefore, the registrant must submit the following studies conducted in accordance with the Agency testing guidelines: acute oral, acute dermal, acute inhalation, primary eye irritation, primary skin irritation and dermal sensitization study.

LABELING: Comments reserved until outstanding data is submitted.

IRB BRANCH REVIEW - TSS

Record Number(s)

D160836

IN 2/1/91 OUT 3/7/91

EFFICACY

FILE OR REG. NO. 12455-AR

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED 1/28/91

DATE OF SUBMISSION 1/24/91

DATE SUBMISSION ACCEPTED 2/1/91

TYPE PRODUCTS(S): I, D, H, F, N, RX S

DATA ACCESSION NO(S). 416490-01, 416490-02

PRODUCT MGR. NO. 16

PRODUCT NAME(S) LIQUA-TOX II

COMPANY NAME Bell Laboratories, Inc.

SUBMISSION PURPOSE registration, buttress efficacy studies submitted in the past

CHEMICAL & FORMULATION 1.06% Sodium Salt of Diphacinone liquid concentrate

Efficacy Review: LIQUA-TOX II, 12455-AR
Bell Laboratories, Inc.
Madison, WI 53704

200.0 INTRODUCTION

200.1 Uses

A 1.06% Sodium Salt of Diphacinone liquid concentrate proposed for registration for mixing into water baits for control of Norway rats, roof rats, and house mice

"in homes; industrial, agricultural, and commercial buildings; and in similar man-made structures."

200.2 Background Information

See product jacket, especially efficacy reviews of 6/19/90, 10/19/90, and 11/20/90. The current submission includes a letter of 1/24/91 to which are appended copies of "raw" data sheets pertaining to fluid consumption in the efficacy tests discussed in my review of 11/20/91. Those efficacy studies were not accepted at that time largely because these raw data sheets were missing.

201.0 DATA SUMMARY

The raw data sheets square with the fluid consumption data reported in the efficacy studies discussed in the efficacy review of 11/20/90. The sheets do indicate, however, that Bell determined consumption to the nearest whole milliliter, not to the nearest 0.1 ml as the summary sheet submitted earlier implied.

In its letter of 1/24/91, Bell states that, in agreement with a comment in EPA's letter of 1/8/91 (and the efficacy review of 11/20/91), it will use additional waterers in future studies with liquid baits to reduce the chances that any waterers would be completely drained by test animals in one day. In the rat test, waterers were completely drained on several occasions. As most of these involved waterers containing test bait, the net effect on the test probably was a slight reduction in the bait acceptance score.

In its letter of 1/24/91, Bell also states that its future reports of studies with liquid baits will include diagrams of test enclosures. Bell did not, however, provide diagrams of the enclosures used in the tests reported previously. Bell claims that the rats used in this test were run in single-sex subgroups. Although the test report states that such a procedure was used, the data tables presented do not indicate which containers were used in the

female group and which were used in the male group. Any sex differences in bait acceptance would be masked by such reporting.

Significantly, Bell's letter of 1/24/91 does not include a promise not to stop future efficacy studies as soon as 100% mortality is observed in the test groups. While stopping tests when all test-group subjects are dead is permitted (practically encouraged) by Protocols 1.201 and 1.202, such a procedure represents "bad science." It defeats the purpose of the control groups, which is to determine whether conditions in the laboratory would cause undue levels of mortality during the prescribed test period. From a registrant's perspective, there is nothing to gain and much to lose through continuing to monitor the control group. Extending the study increases costs, ties up laboratory facilities and personnel for longer periods of time per study, and increases the likelihood that the study could be negated due to the death of more than two control group animals. With these incentives for early termination, the only way for EPA to make sure that studies are taken to term would be to require registrants to do so.

In its letter of 1/24/91, Bell claims to have provided to EPA its "packaging specifications" for this product in a letter of 12/10/90. As I have not seen such a letter, I cannot comment on its alleged content. In its letter of 9/4/90, Bell Described the packaging to be used for this product as a "3 1/4 inch x 4 1/4 inch pouch containing 1.68 fl. oz. of product." These would be packed 50 to a carton. It is not clear whether they would be sold in 50-pouch lots or as individual pouches. What is clear is that this type of packaging would not be satisfactory. There is too great a chance that pouches would be punctured accidentally and too great a chance that their contents would be spilled while users (which could include the general public) were attempting to mix baits. If the product is to be sold in 50-pouch lots, the product label should also appear on the carton.

The use directions on the label submitted on 10/1/90 are acceptable, provided that this product is sold in suitable packaging, which the proposed 1.68-oz pouches are not.

202.0 CONCLUSIONS

1. With support of the raw data sheets provided with your letter of January 24, 1991, the efficacy studies submitted on October 1, 1990, are acceptable. MRID numbers for these tests are 416490-01 for the house mouse test and 416490-2 for the Norway rat test.

2. We are pleased to learn that your future reports of studies of liquid baits will include diagrams of how food containers, waterers and shelter areas are arranged in animal enclosures, and that you will make every attempt to provide sufficient numbers of waterers for all study groups. We also expect that all of your efficacy tests will be continued for their scheduled durations even if all test-group animals have died.

   We further expect that you will use single-sex subgroups for all tank tests and that you will report results obtained in these tests for each sex and subgroup as well as for the test group as a whole. Although you claimed to have caged sexes separately for the rat test run for Liquatox II, you did not distinguish male results from female results in your test report or on your raw data sheets.

[NOTE TO PM:

While the proposed directions for use on the product label are acceptable, I do not believe that this product should be registered unless it is packaged in something more durable and otherwise suitable than 1.68 fl. oz. plastic pouches. Bell claims to have submitted packaging information on 12/10/90. You should find out what our CRP specialists think of this packaging before you consider stamping the labels. If this product is to be sold in lots of 50 (or any other number) in a carton, the carton must also bear a label. This label should correspond to that used for the smaller package except for differences in "net contents" statements.]

William W. Jacobs
Principal Specialist: Rodenticides
Insecticide-Rodenticide Branch
March 7, 1991

Liqua-Tox II

Mix contents of pouch with 1 quart of water.

ACTIVE INGREDIENT:
Sodium Salt of Diphacinone — 2-Diphenylacetyl-1,3-indandione. 0.106%
INERT INGREDIENTS 99.894%
TOTAL 100.00%

CAUTION
KEEP OUT OF REACH OF CHILDREN
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION

Keep away fom children, pets, and domestic animals and wildlife. Do not expose bait where humans, livestock, poultry, pets, or wildlife can drink it. Treated baits should be placed in locations not accessible to children, pets, wildlife, domestic animals, or in tamper-proof bait boxes. Do not contaminate water by cleaning of equipment or disposal of wastes. Apply this product only as specified on this label.

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If swallowed by humans, domestic animals, or pets, this material may reduce the clotting ability of the blood and cause bleeding. In such case intramuscular and oral administrations of Vitamin K1 combined with blood transfusions are indicated as in the case of hemorrhage caused by overdoses of bishydroxycoumarin.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS: This product may be used to control Norway rats (Rattus norvegicus), roof rats (R. rattus), and house mice (Mus musculus) in homes; in industrial, agricultural, and commercial buildings; and in similar manmade structures. Place LIQUA-TOX II in locations not accessible to children, pets, domestic animals, and nontarget wildlife, or in secured, tamper-proof bait stations equipped for dispensing liquid rodenticide baits. Do not use LIQUA-TOX II in any area where there is a possibility of contaminating food or surfaces that come in direct contact with food.

MIXING DIRECTIONS: Thoroughly mix contents of one 1.68 fl. oz. package in 1 quart (32 fluid ounces) of water.

SELECTION OF TREATMENT AREAS: Determine areas where rats and mice will most likely find and consume bait. Generally, these areas are along walls, by gnawed openings, beside burrows, in corners and concealed places, between floors and walls, or in other locations where signs of rats and mice have been seen.

APPLICATION DIRECTIONS:

Norway and Roof Rat: Provide a minimum of 1 pint (16 fluid ounces) of LIQUA-TOX II in each dispenser (suitably-equipped bait station, chick fount, or other suitable device). If infested area is large, or if rat population appears to be high, use dispensers at several locations. Space dispensers and refill them as needed to ensure that bait is exposed in all infested areas where it can be used without putting nontarget organisms at risk.

House mice: Provide 1/2-pint (8 fluid ounces) placements of LIQUA-TOX II in suitably-equipped bait stations, chick founts, or other appropriate vessels. Place dispensers at intervals of 8-12 feet in all infested areas where bait can be used without putting nontarget organisms at risk.

Additional Directions for Rats and Mice: Replace contaminated or spoiled bait immediately. Collect and properly dispose of dead animals and bait that is no longer needed. Continue treatments as long as target species are being controlled by bait and nontarget species are not at risk.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

STORAGE: Store only in original container, in a dry place inaccessible to children and pets.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Securely wrap original container in several layers of newspaper and discard in trash.

EPA Est. No. 12455-WI-1 EPA Reg. No. 12455-AR-1

NET CONTENTS: 1.68 Fl. Oz. (49.68 ml.)

Bell Laboratories, Inc.
3699 Kinsman Boulevard, Madison, Wisconsin 53704

Bell Laboratories, Inc.
3699 Kinsman Boulevard, Madison, Wisconsin 53704 U.S.A. / 608/241-0202 / Fax: 608/241-9631

January 24, 1991

FEDERAL EXPRESS
834 194 7821

Marilyn Mautz
Acting Product Manager (16)
Office of Pesticide Programs - H7505C
U.S. Environmental Protection Agency
401 M. Street, Southwest
Washington, D.C. 20460

RE: LIQUA-TOX II
EPA File Symbol 12455-AR
Your Letter Dated January 8, 1991

Dear Ms. Mautz:

Enclosed per your request please find copies of the raw data sheets for both rats and mice which show the fluid consumption for each tank.

In future reports of studies of liquid baits, we will include a diagram of the test set-up. Please note that we have already allowed the rats to be in single-sex subgroups. We shall also provide more waterers in both the test and control groups so that individual waterers are not completely emptied.

Lastly, we have previously replied to your letter of October 31, 1990 and have supplied you with our packaging specifications in our letter of December 10, 1990.

If you should have any questions regarding this matter, please do not hesitate to contact us. We look forward to your review.

Sincerely,

Bell Laboratories, Inc.

Victoria J. Kriesel

Victoria J. Kriesel
Registration Specialist

VJK:pml

Enclosures

Sample *Liquatox II*
Log # *M1418*
Batch # *22509*
Cage Rack # *cow tank*
Tested *20*

Test No. *Bell Labs, SOP B108 (8-9-90) EPA test method 1.202 (2-26-78)*

Type of Bait *Anticoagulant Liquid*

Test Date: *8-31-90*
Species: *Swiss Webster*
*Animal Log # *A814904*

Bait Consumed	Test Days															TOTALS	
*All weights recorded in ml	1 *79.5%*	2 *90.9%*	3 *89.2%*	4 *86.2%*	5 *62.5%*	6 *100%*	7 *50%*	8 *50%*	9	10	11	12*	13	14	15	ml	Bait %
Treated	*97*	*110.0*	*83.0*	*25.0*	*5.0*	*1.0*	*1.0*	*1.0*								*323.0*	*85.4%*
Control	*25*	*11.0*	*10.0*	*4.0*	*3.0*	*0.0*	*1.0*	*1.0*								*55.0*	*14.6%*
Total	*122*	*121.0*	*43.0*	*29.0*	*8.0*	*1.0*	*2.0*	*2.0*								*378.0*	
(♂) Males Mortality (♀) Females ** All weights recorded in grams			*♂ #7 21.2*	*♀'s #7 24.6 #8 26.2 ♂'s #2 30.7 #6 31.2 #10 24.4*	*♀'s #3 26.9 #4 27.9 #9 27.3 ♂'s #4 27.7 #8 25.0*	*♀'s #2 27.2 #5 25.5 #6 23.3 #10 24.4 ♂'s #3 23.4*	*♂ #5 26.7 #9 21.8*	*♀ #1 23.0 ~~#2 ♂~~ ♂ #1 25.7*									No. Killed *20/20*
Percent Mortality			*5%*	*25%*	*25%*	*25%*	*10%*	*10%*									*100%*

Discussion: *The animals were obtained from Ace Animals, Boyertown, PA. This test was conducted according to Bell Laboratories, SOP B108 (8-9-90) referenced from EPA test method 1.202 (2-26-78). The mice were group caged during acclimation and testing periods. EPA diet #E60 was provided ad lib.*

Conclusion: *Of total liquid diet consumed, the mice drank 85.4% of the treated material, resulting in 100% mortality within 8 days. Control animals remained healthy throughout the test period.*

Test Conducted by *[signatures]*
Date *9-8-90*

Rodenticide Acceptability Assay

Daily Consumption

Date 8-31-90

Species Swiss Webster Log # M1418 Batch # 22509

Control Material Tap H_2O Test Material Liquatox II

Bottle #	1	2	3	4	5	6					*All Weights recorded in mls	
Sex											Daily Total	Test Day
Body Wt.												
Test	6	6	25	40	9	11					97	1
Control	2	5	4	10	2	2					25	
Test	20	49	7	53	10	1					110	2
Control	2	4	1	2	1	1					11	
Test	12	5	1	47	8	10					83	3
Control	2	0	3	2	0	3					10	
Test	1	11	6	1	0	6					25	4
Control	2	0	1	1	0	0					4	
Test	1	0	1	1	1	1					5	5
Control	1	0	1	0	0	1					3	
Test	0	0	0	0	1	0					1	6
Control	0	0	0	0	0	0					0	
Test	0	0	0	0	1	0					1	7
Control	0	0	0	1	0	0					1	
Test	0	0	0	1	0	0					1	8
Control	0	1	0	0	0	0					1	
Test												9
Control												
Test												10
Control												
Test												11
Control												
Test												12
Control												
Test												13
Control												
Test												14
Control												
Test												15
Control												
Total Test												
Total Control												
Day of Death												
Body Wt./Death												

V-POC

Bell Laboratories, Inc.

DAILY FOOD CONSUMPTION
FOR
RATS & MICE

LOG # M1418
BATCH # 22509

*Bottle weights recorded in ml.
*Death weights recorded in grams

DAY # 0	BOTTLE #	TEST	NEW	TAP H_2O	NEW	BOTTLE #	TEST	NEW	TAP H_2O	NEW
8-31-90	1		100		100	4		100		100
	2		100		100	5		100		100
	3		100		100	6		100		100

Results performed by:

Control Animal Status

T= H=

DAY # 1	BOTTLE #	TEST	NEW	TAP H_2O	NEW	BOTTLE #	TEST	NEW	TAP H_2O	NEW
9-1-90	1	94	100	98	100	4	60	100	90	100
	2	91	100	95	100	5	91	100	98	100
	3	75	100	96	100	6	84	100	98	100

Results performed by: Tanis Flood

Control Animal Status
healthy + alert

T=21°C H=53%

DAY # 2	BOTTLE #	TEST	NEW	TAP H_2O	NEW	BOTTLE #	TEST	NEW	TAP H_2O	NEW
9-2-90	1	80	100	98	100	4	47	100	98	100
	2	81	100	96	100	5	90	100	99	100
	3	93	100	99	100	6	99	100	99	100

Results performed by: Tanis Flood

Control Animal Status
lively + inquisitive

T=21°C H=53%

DAY # 3	BOTTLE #	TEST	NEW	TAP H_2O	NEW	BOTTLE #	TEST	NEW	TAP H_2O	NEW
9-3-90	1	88	100	98	100	4	53	100	98	100
	2	95	100	100	100	5	92	100	100	100
	3	99	100	97	100	6	90	100	97	100

Results performed by: Tanis Flood

Control Animal Status
active + curious

T= 21°C H=52%

Bell Laboratories, Inc.

*Bottle weights recorded in ml.
*Death weights recorded in grams

DAILY FOOD CONSUMPTION FOR RATS & MICE

LOG # M1418
BATCH # 22509

DAY #	BOTTLE #	TEST	NEW	TAP H_2O	NEW	BOTTLE #	TEST	NEW	TAP H_2O	NEW
4										
9-4-90	1	99	100	98	100	4	99	100	99	100
	2	89	100	100	100	5	100	100	100	100
	3	94	100	99	100	6	94	100	100	100

Results performed by: Paula [signature]
Control Animal Status: alert + lively
T=21°C H=53%

DAY #	BOTTLE #	TEST	NEW	TAP H_2O	NEW	BOTTLE #	TEST	NEW	TAP H_2O	NEW
5										
9-5-90	1	99	100	99	100	4	99	100	100	100
	2	100	100	100	100	5	99	100	100	100
	3	99	100	99	100	6	99	100	99	100

Results performed by: J. Shavlik
Control Animal Status: vigorous + vibrant
T= 22°C H= 50%

DAY #	BOTTLE #	TEST	NEW	TAP H_2O	NEW	BOTTLE #	TEST	NEW	TAP H_2O	NEW
6										
9-5-90	1	100	100	100	100	4	100	100	100	100
	2	100	100	100	100	5	99	100	100	100
	3	100	100	100	100	6	100	100	100	100

Results performed by: Paula [signature]
Control Animal Status: inquisitive + healthy
T=24°C H=50%

DAY #	BOTTLE #	TEST	NEW	TAP H_2O	NEW	BOTTLE #	TEST	NEW	TAP H_2O	NEW
7										
9-7-90	1	100	100	100	100	4	100	100	99	100
	2	100	100	100	100	5	99	100	100	100
	3	100	100	100	100	6	100	100	100	100

Results performed by: J. Shavlik
Control Animal Status: active + alert
T=21°C H= 51%

COPY

Bell Laboratories, Inc.

*Bottle weights recorded in ml.
*Death weights recorded in grams

DAILY FOOD CONSUMPTION
FOR
RATS & MICE

LOG # M1418
BATCH # 22509

DAY #	BOTTLE #	TEST	NEW	TAP H_2O	NEW	BOTTLE #	TEST	NEW	TAP H_2O	NEW
8										
9-8-92	1	100		100		4	99		100	
	2	100		99		5	100		100	
	3	100		100		6	100		100	

Results performed by: [signature] Control Animal Status curious + healthy T= 20°C H= 50%

DAY #	BOTTLE #	TEST	NEW	TAP H_2O	NEW	BOTTLE #	TEST	NEW	TAP H_2O	NEW

Results performed by: Control Animal Status T= H=

DAY #	BOTTLE #	TEST	NEW	TAP H_2O	NEW	BOTTLE #	TEST	NEW	TAP H_2O	NEW

Results performed by: Control Animal Status T= H=

DAY #	BOTTLE #	TEST	NEW	TAP H_2O	NEW	BOTTLE #	TEST	NEW	TAP H_2O	NEW

Results performed by: Control Animal Status T= H=

COPY

Sample Liquatox II
Log # 1388
Batch # 22509
Cage Rack # Low bank
Tested 20

Test No.
Bell Labs, SOP B107(8-9-90)
EPA test method 1.201 (8-15-80)

Type of Bait
Anticoagulant liquid

Test Date: 8-31-90
Species: Wistar
*Animal Log # A814902

Bait Consumed	Test Days														TOTALS	
*All weights recorded in ml	1 49.2%	2 51.5%	3 53.7%	4 41.5%	5 13.9%	6 23.5%	7	8	9	10	11	12	13	14	15	ml	Bait %
Treated	348.0	358.0	336.0	93.0	11.0	4.0	1.0									1,181	49.0%
Control	360.0	365.0	240.0	131.0	68.0	13.0	3.0									1,230	51.0%
Total	708.0	753.0	626.0	224.0	79.0	17.0	4.0									2,411	
(♂)Males Mortality (♀)Females ** All weights recorded in grams			♂'s #3 277.7 #8 252.2	♀'s #3 228.8 ♂'s #1 299.4 #5 256.2 #6 271.7 #7 290.9 #9 266.6	♀'s #2 181.5 #4 177.6 #9 175.9 ♂'s #2 251.1 #10 315.3	♀'s #1 177.0 #5 176.8 #6 117.2 #7 198.4 #8 182.9 #10 181.6 ♂'s	♂'s #5 223.2										No. Killed 20/20
Percent Mortality			10%	30%	25%	30%	5%										100%

COPY

Discussion: These [redacted] animals were obtained from Ace Animals, Boyertown, PA. This test was conducted according to Bell Laboratories [redacted] B107 (8-9-90) referenced from EPA test method 1.201 (8-15-80). The rats were group caged, sexes separate during acclimation + testing periods. Rodent Blocks were provided [redacted] ad lib. Protocol #LT/0990/B107 was followed.

Conclusion: [redacted] total liquid diet consumed, the rats drank 49.0% of the treated material, resulting in 100% mortality within 7 days. Control animals remained healthy throughout the test period.

Test Conducted by Paul [signature] Jack [signature]
Date 9-7-90

Rodenticide Acceptability Assay
Daily Consumption

Date 8-31-90

Species Wistar Log # 1388 Batch # 22509

Control Material Tap H_2O Test Material Liquatox II

Bottle #	1	2	3	4	5	6					*All Weights recorded in mls	
Sex											Daily Total	Test Day
Body Wt.												
Test	25	37	26	100	82	78					348	1
Control	82	15	74	85	4	100					360	
Test	27	42	100	100	19	100					388	2
Control	15	45	92	90	69	54					365	
Test	26	81	11	90	49	79					336	3
Control	81	9	38	87	70	5					290	
Test	47	8	30	3	3	2					93	4
Control	5	46	32	42	0	6					131	
Test	7	0	2	2	0	0					11	5
Control	20	25	5	17	0	1					68	
Test	1	0	1	1	0	1					4	6
Control	0	1	10	0	1	1					13	
Test	0	0	0	1	0	0					1	7
Control	0	0	0	0	1	2					3	
Test												8
Control												
Test												9
Control												
Test												10
Control												
Test												11
Control												
Test												12
Control											[illegible]	
Test												13
Control										[illegible]	[illegible]	
Test										[illegible]	[illegible]	14
Control										[illegible]	[illegible]	
Test										[illegible]		15
Control											[illegible]	
Total Test											[illegible]	
Total Control												
Day of Death												
Body Wt./Death												

Bell Laboratories, Inc.

DAILY FOOD CONSUMPTION
FOR
RATS & MICE

*Bottle weights recorded in ml.
*Death weights recorded in grams

LOG # 1388
BATCH # 72509

DAY # 0	BOTTLE #	TEST	NEW	TAP H_2O	NEW	BOTTLE #	TEST	NEW	TAP H_2O	NEW
8-31-90	1		100		100	4		100		100
	2		100		100	5		100		100
	3		100		100	6		100		100

Results performed by: Paula Flavell
Control Animal Status: vibrant + curious
T=22°C H=52%

DAY # 1	BOTTLE #	TEST	NEW	TAP H_2O	NEW	BOTTLE #	TEST	NEW	TAP H_2O	NEW
9-1-90	1	75	100	18	100	4	0	100	15	100
	2	63	100	85	100	5	18	100	96	100
	3	74	100	26	100	6	22	100	0	100

Results performed by: Paula Flavell
Control Animal Status: healthy + alert
T=22°C H=53%

DAY # 2	BOTTLE #	TEST	NEW	TAP H_2O	NEW	BOTTLE #	TEST	NEW	TAP H_2O	NEW
9-2-90	1	73	100	85	100	4	0	100	10	100
	2	58	100	55	100	5	81	100	31	100
	3	0	100	8	100	6	0	100	46	100

Results performed by: Paula Flavell
Control Animal Status: lively + inquisitive
T= 22°C H=52%

DAY # 3	BOTTLE #	TEST	NEW	TAP H_2O	NEW	BOTTLE #	TEST	NEW	TAP H_2O	NEW
9-3-90	1	74	100	19	100	4	10	[illegible]	13	[illegible]
	2	19	100	91	100	5	51	[illegible]	30	[illegible]
	3	89	100	62	100	6	21	100	95	[illegible]

Results performed by: Paula Flavell
Control Animal Status: active + curious
T=21°C H=54%

Bell Laboratories, Inc.

DAILY FOOD CONSUMPTION FOR RATS & MICE

*Bottle weights recorded in ml.
*Death weights recorded in grams

LOG # 1558

BATCH # 22509

DAY # 4	BOTTLE #	TEST	NEW	TAP H_2O	NEW	BOTTLE #	TEST	NEW	TAP H_2O	NEW
9-4-90	1	53	100	95	100	4	97	100	58	100
	2	92	100	54	100	5	97	100	100	100
	3	70	100	68	100	6	98	100	94	100

Results performed by: Tank Bland

Control Animal Status alert + curious

T= 22°C H= 54%

DAY # 5	BOTTLE #	TEST	NEW	TAP H_2O	NEW	BOTTLE #	TEST	NEW	TAP H_2O	NEW
9-5-90	1	93	100	80	100	4	98	100	83	100
	2	100	100	75	100	5	100	100	100	100
	3	98	100	95	100	6	100	100	99	100

Results performed by: Shawn

Control Animal Status healthy + alert

T= 23°C H= 52%

DAY # 6	BOTTLE #	TEST	NEW	TAP H_2O	NEW	BOTTLE #	TEST	NEW	TAP H_2O	NEW
9-6-90	1	99	100	100	100	4	99	100	100	100
	2	100	100	99	100	5	100	100	99	100
	3	99	100	90	100	6	99	100	99	100

Results performed by: Shawn

Control Animal Status vigorous + vibrant

T= 22°C H= 52%

DAY # 7	BOTTLE #	TEST	NEW	TAP H_2O	NEW	BOTTLE #	TEST	NEW	TAP H_2O	NEW
9-7-90	1	100		100		4	99		100	
	2	100		100		5	100		99	
	3	100		100		6	100		98	

Results performed by: Tank Bland

Control Animal Status inquisitive + alert

T= 23°C H= 50%

JAN 8 1991

Bell Laboratories, Inc.
3699 Kinsman Boulevard
Madison, WI 53704

5384535

Gentlemen:

Subject: Liqua-Tox II
EPA File Symbol 12455-AR
Your Letter Dated October 1, 1990

We have the following comments about the efficacy data (MRID Nos. 416490-01 and -02) submitted with the above letter:

1. Although the results reported suggest good acceptance and acceptable mortality in test groups, review of efficacy data submitted cannot be completed until copies of raw data sheets and sheets which show fluid consumption data for each tank are provided for our review.

2. Future reports of studies of liquid baits should include diagrams of how food containers, waterers, and shelter areas were arranged in animal enclosures. These enclosures should be laid out similarly for all study groups. Single-sex subgroups are desirable for tank tests, particularly when the enclosures used are on the small end of the range prescribed by the protocol.

   In future rat studies with liquid baits, you should provide at least two more waterers per fluid per enclosure for test groups and a total number of waterers in each control-group enclosure that equals the total number of waterers used in each test-group enclosure. In other words, if you use five waterers for bait and five for water in each test-group enclosure, you should use ten waterers in each control-group enclosure. In the rat test reported on October 1, 1990, there were too many instances when individual waterers were completely emptied.

61181:I:Cromwell:L16-3:KENCO:12/21/90:01/20/91:DD:vo:jh

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

EPA Form 1320-1 (12-70) OFFICIAL FILE COPY

3. The proposed directions for use on the product label are acceptable. However, this product cannot be registered until the efficacy issues discussed above and the packaging problem addressed in our letter of October 31, 1990 are resolved.

Pursuant to Section 152.105 of Title 40 of the Code of Federal Regulations, if the above requested information, or a written request for additional time (indicate amount) is not submitted to the Registration Division within 75 days of the date of the receipt of this notice, the application will be administratively withdrawn. In that event, any subsequent submission relating to the same product must be submitted as a new application.

Sincerely yours,

Marilyn A. Mautz
Acting Product Manager (16)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Bell Laboratories, Inc.
3699 Kinsman Boulevard, Madison, Wisconsin 53704 U.S.A. / 608/241-0202 / Fax: 608/241-9631

December 10, 1990

FEDERAL EXPRESS # 8341947445

Ms. Marilyn A. Mautz
Acting Product Manager
Insecticide - Rodenticide Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
Washington, D.C. 20460

Subject: LIQUA-TOX II
EPA File Symbol 12455-AR
Your letter dated October 31, 1990

Dear Ms. Mautz:

The product LIQUA-TOX II is packaged in 3 1/4" x 4 1/4" plastic film pouches each containing 1.68 fluid ounces. The film is made up of three different types of plastic resins, each serving a specific function. Please see the enclosed letter from Stearns Packaging Corporation; it outlines the make-up and reasoning for using this particular packaging.

Two rows of 36 pouches are then packaged in a single carton of corrugated cardboard. These cardboard boxes are rated for 200 lb/in^2 Bursting Test and Gross Weight of 65 lb. Into each box is packaged only 2 x 36 x 1.68 ounces = 7.56 lbs. The rating is 200 c where c represents the largest sized flute of standard corrugated boxes. This larger flute, or ripple, lends the package a stronger stacking strength and provides additional protection against accidental puncture.

The pouches are not placed into these boxes for at least 12 hours after filling so as to ensure that none of the pouches leak. Each pouch is filled to only approximately 60% of its total volume; this large air bubble gives the filled pouch extra flexibility to resist punctures. We have used this packaging for almost 10 years without incident.

Please also note that the pouches are not notched so the heat-sealed seams are not weakened. On the upper right-hand corner of each pouch is printed "Cut Here". The cut, rather than a tear, provides for a more controlled pouring of the concentrate during the mixing process.

If you have any further questions regarding this matter, please contact me.

Sincerely,

Bell Laboratories, Inc.

Art Smith
VP Research & Development

AS/ajb

Enclosures

STEARNS®

STEARNS PACKAGING CORPORATION

4200 SYCAMORE AVENUE
MADISON, WISCONSIN 53704

P.O. BOX 3216
TELEPHONE (608) 246-5150
FAX (608) 246-5149

November 13, 1990

Kolby Hirth
Bell Labs
3699 Kinsman Blvd.
Madison, WI 53704

Dear Kolby:

At your request I am writing to detail the integrity and performance of our proprietary liquid pouching systems.

This very system, used to package your Liquatox product, depends on the compatibility of its machinery with the special packaging film to produce tough, leak proof pouches.

The film has three laminations of different plastic resins; each with its own performance properties.

The outer lamination is a barrier against vapor transmission from inside the pouch. It must also be dimensionally stable and ink-receptive to assure clear, sharp print quality and accurate registration of the various print colors. The printing is done on the back of the lamination (reverse print) and then laminated to the center layer to protect it from abrasion and chemical attack.

The center lamination imparts "toughness" to the finished package to make it tear and puncture-restistant.

The inner lamination, which contacts the actual product, is chosen for its chemical resistance and adhesion properties to prevent leakage in transit and in long term storage.

Stearns Packaging Corporation has been applying this technology to the packaging of corrosive, EPA-registered sanitizer concentrates for over 12 years with virtually no leakage; our record with plastic bottles has been far less satisfactory. Bell Laboratories has been using our system for the better part of 10 years and no complaints have come to my attention.

Regards

John B. Everitt

John B. Everitt

JBE/llk

IRB BRANCH REVIEW - TSS

Record Number(s)

D157224
S384535

IN 10/24/90 OUT 11/20/90

EFFICACY

FILE OR REG. NO. 12455-61

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED 10/4/90

DATE OF SUBMISSION 10/1/90

DATE SUBMISSION ACCEPTED 10/24/90

TYPE PRODUCTS(S): I, D, H, F, N, R, X S

DATA ACCESSION NO(S). 416490-01, 416490-02

PRODUCT MGR. NO. 16

PRODUCT NAME(S) LIQUATOX II

COMPANY NAME Bell Laboratories, Inc.

SUBMISSION PURPOSE registration

CHEMICAL & FORMULATION 1.06% Sodium Salt of Diphacinone liquid concentrate

Efficacy Review: LIQUA-TOX II, 12455-AR
Bell Laboratories, Inc.
Madison, WI 53704

200.0 INTRODUCTION

200.1 Uses

A 1.06% Sodium Salt of Diphacinone liquid concentrate proposed for registration for mixing into water baits for control of Norway rats, roof rats, and house mice

"in homes; industrial, agricultural, and commercial buildings; and in similar man-made structures."

200.2 Background Information

See product jacket, especially efficacy reviews of 6/19/90 and 10/19/90. The current submission includes new efficacy studies, to replace those previously rejected by EPA; revised proposed labels; and a cover letter. As noted in the prior efficacy reviews, the original efficacy studies were not acceptable.

201.0 DATA SUMMARY

The efficacy studies were run by Bell at its Madison facilities. Test subjects were Wistar strain laboratory Norway rats and Swiss Webster strain laboratory house mice. Tests were said to have been run according to EPA's Protocols 1.201 and 1.202 for rats and mice, respectively. In the rat test, animals apparently were housed in 10-animal sex-segregated subgroups. This procedure is acceptable (desirable, actually) for "tank" type tests.

"Raw" data sheets were not included with either study report.

The quality assurance report for the rat test suggests that only three 100-ml waterers were used in the tank for the control group's females. Four such waterers were used for the tank that contained the control group's males. Although as many as six of seven waterers used for the control group were depleted on test days, all control-group animals survived. The processed sheet which reports consumption from the waterers does not indicate which sex was drinking from which bottles. The report also fails to indicate how waterers were deployed in test enclosures ("cow tanks").

Five waterers were completely drained in a day by test-group subjects over the first two days of exposure to bait and plain water in the test group. As four of these five instances involved bait bottles, it is possible that the level of bait Acceptance observed in this study would have been higher than the 49% reported if larger quantities of both fluids had been offered.

No deviations from protocol were reported in the quality assurance report for the mouse test. Animals in this test were housed in 20-animal, mixed-sex groups.

A chemical analysis of the product batch used for both tests was conducted by Bell's sister company, Motomco Ltd. This test indicated a Sodium Salt of Diphacinone concentration on 0.112%, a value within acceptable limits of the concentration claimed on the label. Motomco's analysis of the bait mixed from the concentrate product for use in the test detected a Sodium Diphacinone concentration of 0.0052%, which also is an acceptable level.

Reported test results are summarized in Table 1. These data suggest that the product would be very effective in controlling house mice and Norway rats. Acceptance of bait made from the concentrate remained relatively high for the entire mouse study and for the first four days of the rat study. All 20 subjects died in both tests. Both tests were stopped as soon as 100% mortality was observed in their respective test groups. Although this procedure is permitted by Protocols 1.201 and 1.202, I do not think it appropriate as it defeats the purpose of the control groups, which is to determine whether conditions in the laboratory would cause undue levels of mortality during the prescribed test period.

The label submitted on 10/1/90 in similar to that which I found to be acceptable in the efficacy review of 10/19/90. The label contains bait protection language in two locations: the precautionary labeling section and the "USE RESTRICTIONS" portion of the "DIRECTIONS FOR USE." As the information in these sections is not contradictory, I suggest that the language remain as it is. If Bell seeks to delete text from one of these sections, it should come out of the precautionary section and remain in "USE RESTRICTIONS."

202.0 CONCLUSIONS

1. Although the results reported suggest good acceptance and acceptable Mortality in test groups, review of efficacy data submitted cannot be completed until copies of raw data sheets and sheets which show fluid

consumption data for each tank are provided for our review.

Future reports of studies of liquid baits should include diagrams of how food containers, waterers, and shelter areas were arranged in animal enclosures. These enclosures should be laid out similarly for all study groups. Single-sex subgroups are desirable for tank tests, particularly when the enclosures used are on the small end of the range prescribed by the protocol.

In future rat studies with liquid baits, you should provide at least two more waterers per fluid per enclosure for test groups and a total number of waterers in each control-group enclosure that equals the total number of waterers used in each test-group enclosure. In other words, if you use five waterers for bait and five for water in each test-group enclosure, you should use ten waterers in each control-group enclosure. In the rat test reported on October 1, 1990, there were too many instances when individual waterers were completely emptied.

3. The proposed directions for use on the product label are acceptable. This product cannot be registered, however until the efficacy issues discussed above and the packaging problem addressed in our letter of October 31, 1990, are resolved.

William W. Jacobs
Principal Specialist: Rodenticides
Insecticide-Rodenticide Branch
~~[illegible]~~, 1990
November 20

TABLE 1. RESULTS OF GROUP-CAGED LABORATORY EFFICACY TESTS OF LABORATORY RATS AND MICE WITH 12455-AR (data submitted 10/1/90).

SPECIES [TEST #]	STRAIN	TEST DAY	ml BAIT TAKEN	ml CONTROL TAKEN	% BAIT ACCEPTANCE	DEATHS Males	DEATHS Females	DEATHS Total	PERCENT MORTALITY
Norway Rat 0990/B107	Wistar	1	348	360	49.2%	0	0	0	0.0%
		2	388	365	51.5%	0	0	0	0.0%
		3	336	290	53.7%	2	0	2	10.0%
		4	93	131	41.5%	5	1	8	40.0%
		5	11	68	13.9%	2	3	13	65.0%
		6	4	13	23.5%	0	6	19	95.0%
		7	1	3	25.0%	1	0	20	100.0%
		ALL	1181	1230	49.0%	10	10	20	100.0%
House Mouse 0990/B108	Swiss Webster	1	97	25	79.5%	0	0	0	0.0%
		2	110	11	90.9%	0	0	0	0.0%
		3	83	10	89.2%	1	0	1	5.0%
		4	25	4	86.2%	3	2	6	30.0%
		5	5	3	62.5%	2	3	11	55.0%
		6	1	0	100.0%	1	4	16	80.0%
		7	1	1	50.0%	2	0	18	90.0%
		8	1	1	50.0%	1	1	20	100.0%
		ALL	323	55	85.4%	10	10	20	100.0%

Bell Laboratories, Inc.
3699 Kinsman Boulevard, Madison, Wisconsin 53704 U.S.A. / 608/241-0202 / Fax: 608/241-9631

416490-00

October 1, 1990

FEDERAL EXPRESS
#800 679 1973

Mr. William H. Miller
Product Manager (16)
Office of Pesticide Programs-H7505C
U.S. Environmental Protection Agency
401 M. Street, Southwest
Washington, D.C. 20460

RE: LIQUA-TOX II
EPA File Symbol 12455-AR
Our Letter Dated September 4, 1990

Dear Mr. Miller:

Enclosed are the results of efficacy testing on both rats and mice in support of the above mentioned product registration.

Additionally, we have enclosed five copies of proposed labeling, which should be considered instead of the label submitted on September 4, 1990. The labels submitted on September 4th had improper storage and disposal statements. We look forward to hearing from you in the near future. Thank you for your consideration.

Sincerely,

Bell Laboratories, Inc.

Victoria J. Kriesel

Victoria J. Kriesel
Registration Specialist

VJK:pml

Enclosures

Efficacy on mice — 41649001
Efficacy on Rats — 41649002

Liqua-Tox II

Mix contents of pouch with 1 quart of water.

ACTIVE INGREDIENT:
Sodium Salt of Diphacinone — 2-Diphenylacetyl-1,3-indandione. 0.106%
INERT INGREDIENTS 99.894%
TOTAL 100.00%

CAUTION
KEEP OUT OF REACH OF CHILDREN
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION

Keep away fom children, pets, and domestic animals and wildlife. Do not expose bait where humans, livestock, poultry, pets, or wildlife can drink it. Treated baits should be placed in locations not accessible to children, pets, wildlife, domestic animals, or in tamper-proof bait boxes. Do not contaminate water by cleaning of equipment or disposal of wastes. Apply this product only as specified on this label.

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If swallowed by humans, domestic animals, or pets, this material may reduce the clotting ability of the blood and cause bleeding. In such case intramuscular and oral administrations of Vitamin K1 combined with blood transfusions are indicated as in the case of hemorrhage caused by overdoses of bishydroxycoumarin.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS: This product may be used to control Norway rats (Rattus norvegicus), roof rats (R. rattus), and house mice (Mus musculus) in homes; in industrial, agricultural, and commercial buildings; and in similar manmade structures. Place LIQUA-TOX II in locations not accessible to children, pets, domestic animals, and nontarget wildlife, or in secured, tamper-proof bait stations equipped for dispensing liquid rodenticide baits. Do not use LIQUA-TOX II in any area where there is a possibility of contaminating food or surfaces that come in direct contact with food.

MIXING DIRECTIONS: Thoroughly mix contents of one 1.68 fl. oz. package in 1 quart (32 fluid ounces) of water.

SELECTION OF TREATMENT AREAS: Determine areas where rats and mice will most likely find and consume bait. Generally, these areas are along walls, by gnawed openings, beside burrows, in corners and concealed places, between floors and walls, or in other locations where signs of rats and mice have been seen.

APPLICATION DIRECTIONS:

Norway and Roof Rat: Provide a minimum of 1 pint (16 fluid ounces) of LIQUA-TOX II in each dispenser (suitably-equipped bait station, chick fount, or other suitable device). If infested area is large, or if rat population appears to be high, use dispensers at several locations. Space dispensers and refill them as needed to ensure that bait is exposed in all infested areas where it can be used without putting nontarget organisms at risk.

House mice: Provide 1/2-pint (8 fluid ounces) placements of LIQUA-TOX II in suitably-equipped bait stations, chick founts, or other appropriate vessels. Place dispensers at intervals of 8-12 feet in all infested areas where bait can be used without putting nontarget organisms at risk.

Additional Directions for Rats and Mice: Replace contaminated or spoiled bait immediately. Collect and properly dispose of dead animals and bait that is no longer needed. Continue treatments as long as target species are being controlled by bait and nontarget species are not at risk.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

STORAGE: Store only in original container, in a dry place inaccessible to children and pets.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Securely wrap original container in several layers of newspaper and discard in trash.

EPA Est. No. 12455-WI-1 EPA Reg. No. 12455-AR

NET CONTENTS: 1.68 Fl. Oz. (49.68 ml.)

Bell Laboratories, Inc.
3699 Kinsman Boulevard, Madison, Wisconsin 53704

5381758 - 161

OCT 31 1990

Ms. Victoria J. Kriesel
Bell Laboratories, Inc.
3699 Kinsman Boulevard
Madison, WI 53704

Dear Ms. Kriesel:

Subject: Liqua-Tox II
EPA File Symbol 12455-AR
Your Letter Dated September 4, 1990

The efficacy data (MRID Nos. 414718-01 and -02) submitted previously for this product cannot be accepted in light of the various problems noted in your letter of September 4, 1990.

We look forward to receiving reports of the efficacy trials which you expected to complete by October 15, 1990.

The "DIRECTIONS FOR USE" on your revised proposed label for EPA File Symbol 12455-AR acceptable.

We are concerned that the packaging that you proposed to use for this product would not promote its safe shipping and handling. What features of this packaging would mitigate against the spilling of concentrate during mixing operations? What features of this packaging would mitigate against accidental punctures of pouches and provide for containment of any product released as a result of such accidents?

Pursuant to Section 152.105 of Title 40 of the Code of Federal Regulations, if the above requested information, or a written request for additional time is not submitted to the Registration Division within 75 days of the date of the receipt of this notice, the application will be administratively withdrawn. In that event, any subsequent submission relating to the same product must be submitted as a new application.

61857:I:Palmateer:L16-17:KENCO:10/23/90:12/23/90:DD:VO:EK:CL

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

EPA Form 1320-1 (12-70) OFFICIAL FILE COPY

If you have any questions about this letter, contact Steve Palmateer at (703) 557-4408 or 557-2600.

Sincerely yours,

Marilyn A. Mautz
Acting Product Manager (16)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Bell Laboratories, Inc.
3699 Kinsman Boulevard, Madison, Wisconsin 53704 U.S.A. / 608/241-0202 / Fax: 608/241-9631

September 4, 1990

CERTIFIED
P 443 019 420

Mr. William H. Miller
Product Manager(16)
Office of Pesticide Programs-H7505C
U.S Environmental Protection Agency
401 M Street, Southwest
Washington, D.C. 20460

Subject: LIQUA-TOX II, MRID 414718
EPA File No. 12455-AR
Your letter dated June 27, 1990.

Dear Mr. Miller:

In your above mentioned letter, you stated that you needed further information on efficacy data MRID 414718. In response to that letter, the procedures used to determine the readings taken from calibrated bottles are as follows:

1. Calibrated bottle was placed upright on a level surface.

2. Reading was taken from the lowest point of the miniscus line.

3. This value from the reading was then recorded on the form "Daily Food Consumption for Rats and Mice."

4. The amount consumed was determined by subtracting the recorded volume from the "Daily Food Consumption for Rats and Mice" form from the initial volume, which is always 100 ml. For example, if 91 ml was the value read from the calibrated bottle, it would then be recorded on the "Daily Food Consumption for Rats and Mice" form. The amount consumed would be calculated by subtracting 91 ml from the initial volume, 100 ml. Therefore, the amount consumed was 9 ml.

5. Then, the amount consumed (100 ml minus the amount read from the bottle) is recorded on the form "Rodenticide Acceptability Assay Daily Feed Consumption." This form contains the amount consumed in all 12 bottles (6 tests and 6 control) for the 15 day test.

6. Lastly, the 15 days are added up for each of the control and test material and the total volume consumed is placed on the Data Summary Sheet.

Inert ingredient information may be entitled to confidential treatment

However, within the rat efficacy data, the calculated values were inadvertently recorded on the form "Daily Food Consumption for Rats and Mice" instead on the readings from the bottles. Additionally, the mouse efficacy data did not include the form "Rodenticide Acceptability Assay Daily Feed Consumption."

To prepare the bait from concentrate, the label directions were followed. The contents of 1-1.68 fl. oz. package was thoroughly mixed in 1 quart (32 fluid ounces) of water. An analysis of the bait was not conducted.

Therefore, because of these oversights, Bell Laboratories, Inc. will be submitting new rat and mouse efficacy studies in support of this product. Our projected completion date is October 15, 1990.

Regarding Item 2, the product is packaged in an 3 1/4 inch x 4 1/4 inch plastic pouch containing 1.68 fl. oz. of product. Fifty pouches are then packaged into a single carton.

In response to Item 3 in your June 27, 1990 letter, we have revised the label according to your comments and have enclosed 5 copies of the proposed labelling for your review.

Regarding Item 4, please be advised that Bell Laboratories, Inc. is in the process of reregistering Technical Diphacinone and our sister company, Motomco, Ltd, is reregistering Sodium Diphacinone. It is Bell Laboratories, Inc. intent to reference these files for support of this product. As requested please find a copy of the Material Safety Data Sheet for [redacted], which is found in the Confidential Statement of Formula.

Lastly, regarding Item 5, a data matrix for the finished product and correspondence to the matrix has been enclosed.

If you should have any questions regarding these matters, please do not hesitate to contact us. Thank you for your cooperation.

Sincerely,

Bell Laboratories, Inc.

Victoria J Kriesel

Victoria J. Kriesel
Registration Specialist

VJK/ajb
Enclosure

IRB BRANCH REVIEW - TSS

Record Number(s)
D155542
S381758

IN 9/11/90 OUT 10/19/90

EFFICACY

FILE OR REG. NO. 12455-AT

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED 9/10/90

DATE OF SUBMISSION 9/4/90

DATE SUBMISSION ACCEPTED 9/11/90

TYPE PRODUCTS(S): I, D, H, F, N, R, X S

DATA ACCESSION NO(S). no new efficacy data

PRODUCT MGR. NO. 16

PRODUCT NAME(S) LIQUATOX II

COMPANY NAME Bell Laboratories, Inc.

SUBMISSION PURPOSE registration, explanation of procedures in past studies

CHEMICAL & FORMULATION 0.106 Sodium Salt of Diphacinone
concentrate w/ end-use directions

Efficacy Review: LIQUA-TOX II, 12455-AR
Bell Laboratories, Inc.
Madison, WI 53704

200.0 INTRODUCTION

200.1 Uses

A 1.06% Sodium Salt of Diphacinone liquid concentrate proposed for registration for mixing into water baits for control of Norway rats (Rattus norvegicus), roof rats, (R. rattus), and house mice

> "in homes; in industrial, agricultural, and commercial buildings; and in similar man-made structures."

200.2 Background Information

See efficacy review of 6/19/90, along with other information in product jacket. The current submission discusses the comments in the efficacy review of 6/19/90 (which were relayed to Bell via EPA's letter of 6/27/90), revised proposed labels for this product, assorted forms, and a Material Safety Data Sheet for one of the inert ingredients in the product.

200.0 DATA SUMMARY

According to Victoria Kriesel, author of Bell's letter of 9/4/90, Bell has scheduled replacement efficacy studies for those which were discussed in the efficacy review of 6/19/90. In her letter, Kriesel basically admits that Bell made enough mistakes in its conduct of the rat and mouse efficacy studies that the firm itself decided to run new tests. She stated that readings were transcribed on the raw data sheets for house mice but that the calculated amount of liquid consumed was recorded for the rat tests. She also noted that the form entitled "Rodenticide Acceptability Assay Daily Feed Consumption" was omitted from the mouse report and that no chemical analysis of the test ration was conducted. Perhaps, Bell will do better in its next tests.

Kriesel stated that the contents of a single 1.68-oz pouch were mixed with a quart of water to prepare the baits used in the efficacy tests submitted earlier. I am concerned that this pouch would create an unnecessary potential for exposure of the person mixing liquid baits to the 0.106% Sodium Salt of Diphacinone concentrate. The person mixing baits would have to cut or tear a pouch open and empty its contents into a quart of water. For shipping, fifty of these pouches are to be "packaged into a single carton." Neither the shipping

nor the handling of this type of product in the packaging described sounds safe to me. I suggest that Precautionary Labeling personnel be asked to comment upon these issues.

The "DIRECTIONS FOR USE" on the revised proposed labels correspond to the directions dictated in the efficacy review of 6/19/90 and in EPA's letter of 6/27/90.

202.0 CONCLUSIONS

1. The efficacy data submitted previously for this product cannot be accepted in light of the various problems noted in your letter of September 4, 1990.

   We look forward to receiving reports of the efficacy trials which you expected to complete by October 15, 1990.

2. The "DIRECTIONS FOR USE" on your revised proposed label for 12455-AR are acceptable.

3. We are concerned that the packaging that you proposed to use for this product would not promote its safe shipping and handling. What features of this packaging would mitigate against the spilling of concentrate during mixing operations? What features of this packaging would mitigate against accidental punctures of pouches and provide for containment of any product released as a result of such accidents?

William W. Jacobs
Principal Specialist: Rodenticides
Insecticide-Rodenticide Branch
October 19, 1990

Liqua-Tox II

Mix contents of pouch with 1 quart of water.

ACTIVE INGREDIENT:
Sodium Salt of Diphacinone — 2-Diphenylacetyl-1,3-indandione. 0.106%
INERT INGREDIENTS 99.894%
TOTAL 100.00%

CAUTION
KEEP OUT OF REACH OF CHILDREN
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION

Keep away fom children, pets, and domestic animals and wildlife. Do not expose bait where humans, livestock, poultry, pets, or wildlife can drink it. Treated baits should be placed in locations not accessible to children, pets, wildlife, domestic animals, or in tamper-proof bait boxes. Do not contaminate water by cleaning of equipment or disposal of wastes. Apply this product only as specified on this label.

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If swallowed by humans, domestic animals, or pets, this material may reduce the clotting ability of the blood and cause bleeding. In such case intramuscular and oral administrations of Vitamin K1 combined with blood transfusions are indicated as in the case of hemorrhage caused by overdoses of bishydroxycoumarin.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS: This product may be used to control Norway rats (Rattus norvegicus), roof rats (R. rattus), and house mice (Mus musculus) in homes; in industrial, agricultural, and commercial buildings; and in similar manmade structures. Place LIQUA-TOX II in locations not accessible to children, pets, domestic animals, and nontarget wildlife, or in secured, tamper-proof bait stations equipped for dispensing liquid rodenticide baits. Do not use LIQUA-TOX II in any area where there is a possibility of contaminating food or surfaces that come in direct contact with food.

MIXING DIRECTIONS: Thoroughly mix contents of one 1.68 fl. oz. package in 1 quart (32 fluid ounces) of water.

SELECTION OF TREATMENT AREAS: Determine areas where rats and mice will most likely find and consume bait. Generally, these areas are along walls, by gnawed openings, beside burrows, in corners and concealed places, between floors and walls, or in other locations where signs of rats and mice have been seen.

APPLICATION DIRECTIONS:

Norway and Roof Rat: Provide a minimum of 1 pint (16 fluid ounces) of LIQUA-TOX II in each dispenser (suitably-equipped bait station, chick fount, or other suitable device). If infested area is large, or if rat population appears to be high, use dispensers at several locations. Space dispensers and refill them as needed to ensure that bait is exposed in all infested areas where it can be used without putting nontarget organisms at risk.

House mice: Provide 1/2-pint (8 fluid ounces) placements of LIQUA-TOX II in suitably-equipped bait stations, chick founts, or other appropriate vessels. Place dispensers at intervals of 8-12 feet in all infested areas where bait can be used without putting nontarget organisms at risk.

Additional Directions for Rats and Mice: Replace contaminated or spoiled bait immediately. Collect and properly dispose of dead animals and bait that is no longer needed. Continue treatments as long as target species are being controlled by bait and nontarget species are not at risk.

STORAGE AND DISPOSAL

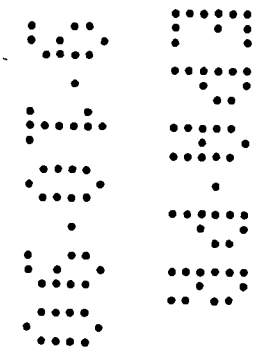
STORAGE: Store only in original container, in a dry place inaccessible to children and pets.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, of, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

EPA Est. No. 12455-WI-1 EPA Reg. No. 12455-AR

NET CONTENTS: 1.68 Fl. Oz. (49.68 ml.)



Pages 146-149 - *Inert ingredient information may be entitled to confidential treatment*

MATRIX FORMAT - DATA REQUIREMENT LISTING FOR THE SELECTIVE METHOD OF SUPPORT

1. PRODUCT NAME: Liqua-Tox II	2. EPA REG.NO./FILE SYMBOL: 12455-AR	3. FORMULATOR'S EXEMPTION SELECTED: YES ____ NO X	4. PAGE 1 OF 4
5. APPLICANT'S (COMPANY) NAME AND ADDRESS: Bell Laboratories, Inc. 3699 Kinsman Blvd. Madison, WI 53704	6. APPLICATION FOR REGISTRATION DATED: June 27, 1988 (MONTH DAY YEAR)	7. NAME OF ACTIVE INGREDIENT(S): Diphacinone, Sodium salt	

8. 40 CFR Part 158 - DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						
8a. Guideline Reference Number	8b. Name of Test	9a. Submitted by Applicant To be submitted	9b. Date Submitted	9c. Submitted by another person/firm (give name)	9d. Certificate of Permission (P) or Offer to Pay (OTP) enclosed: indicate "P" or "OTP"	9e. Public Literature	9f. N.A. or Waiver or other (explain)	10. MRID Number, EPA Accession Number, or other identifying number
Section 158.190	PRODUCT CHEMISTRY							
61-1	Identity of ingredients	X						
61-2	Statement of composition	X						
61-3	Discussion of formation of ingredients						N/A (See attached correspondance)	
62-1	Preliminary analysis						N/A (See attached correspondance)	
62-2	Certification of limits	X						
62-3	Analytical method for enforcement limits	X						
63-2	Color	X						
63-3	Physical State	X						
63-4	Odor	X						

MATRIX FORMAT - DATA REQUIREMENT LISTING FOR THE SELECTIVE METHOD OF SUPPORT

1. PRODUCT NAME: Liqua-Tox II	2. EPA REG.NO./FILE SYMBOL: 12455-AR	3. FORMULATOR'S EXEMPTION SELECTED: YES ____ NO X	4. PAGE 2 OF 4
5. APPLICANT'S (COMPANY) NAME AND ADDRESS: Bell Laboratories, Inc. 3699 Kinsman Blvd. Madison, WI 53704	6. APPLICATION FOR REGISTRATION DATED: June 27, 1988 (MONTH DAY YEAR)	7. NAME OF ACTIVE INGREDIENT(S): Diphacinone, Sodium Salt	

8. 40 CFR Part 158 - DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						
8a. Guideline Reference Number	8b. Name of Test	9a. Submitted by Applicant (To be submitted)	9b. Date Submitted	9c. Submitted by another person/firm (give name)	9d. Certificate of Permission (P) or Offer to Pay (OTP) enclosed: indicate "P" or "OTP"	9e. Public Literature	9f. N.A. or Waiver or other (explain)	10. MRID Number, EPA Accession Number, or other identifying number
Section 158.190	*PRODUCT CHEMISTRY* (continued)							
63-5	Melting point						N/A (See attached correspondance)	
63-6	Boiling point	X						
63-7	Density, bulk-density, or specific gravity	X						
63-8	Solubility	X						
63-9	Vapor Pressure	X						
63-10	Dissociation constant						N/A (See attached correspondance)	
63-11	Octanol/water partition coefficient						N/A (See attached correspondance)	
63-12	pH	X						
63-13	Stability	X						
63-14	Oxidizing/reducing reaction						N/A (See attached correspondance)	

MATRIX FORMAT - DATA REQUIREMENT LISTING FOR THE SELECTIVE METHOD OF SUPPORT

1. PRODUCT NAME: Liqua-Tox II	2. EPA REG.NO./FILE SYMBOL: 12455-AR	3. FORMULATOR'S EXEMPTION SELECTED: YES ____ NO X	4. PAGE 3 OF 4
5. APPLICANT'S (COMPANY) NAME AND ADDRESS: Bell Laboratories, Inc. 3699 Kinsman Blvd. Madison, WI 53704	6. APPLICATION FOR REGISTRATION DATED: June 27, 1988 (MONTH DAY YEAR)	7. NAME OF ACTIVE INGREDIENT(S): Diphacinone, Sodium Salt	

8. 40 CFR Part 158 - DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						
8a. Guide-line Refer-ence Number	8b. Name of Test	9a. Submitted by Applicant To be submitted	9b. Date Submitted	9c. Submitted by another person/firm (give name)	9d. Certificate of Permis-sion (P) or Offer to Pay (OTP) enclosed: indicate "P" or "OTP"	9e. Public Litera-ture	9f. N.A. or Waiver or other (explain)	10. MRID Number, EPA Accession Number, or other identifying number
Section 158.190	PRODUCT CHEMISTRY (continued)							
63-15	Flammability						N/A	(See attached correspondance)
63-16	Explodability						N/A	(See attached
63-17	Storage stability	X						correspondance)
63-18	Viscosity	X						
63-19	Miscibility						N/A	(See attached)
63-20	Corrosion characteristics						N/A	(See attached) correspondance
63-21	Dielectric break-down voltage						N/A	(See attached) correspondance
Section 158.340	TOXICOLOGY							
81-1	Acute oral toxicity: rat					X	(See attached	correspondance)
81-2	Acute dermal toxicity, rabbit						N/A	

MATRIX FORMAT - DATA REQUIREMENT LISTING FOR THE SELECTIVE METHOD OF SUPPORT

1. PRODUCT NAME: Liqua-Tox II	2. EPA REG.NO./FILE SYMBOL: 12455-AR	3. FORMULATOR'S EXEMPTION SELECTED: YES ____ NO X	4. PAGE 4 OF 4
5. APPLICANT'S (COMPANY) NAME AND ADDRESS: Bell Laboratories, Inc. 3699 Kinsman Blvd. Madison, WI 53704	6. APPLICATION FOR REGISTRATION DATED: June 27, 1988 (MONTH DAY YEAR)	7. NAME OF ACTIVE INGREDIENT(S): Diphacinone, Sodium salt	

8. 40 CFR Part 158 - DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						
8a. Guideline Reference Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (give name)	9d. Certificate of Permission (P) or Offer to Pay (OTP) enclosed: indicate "P" or "OTP"	9e. Public Literature	9f. N.A. or Waiver or other (explain)	10. MRID Number, EPA Accession Number, or other identifying number
Section 158.190	TOXICOLOGY (continued)							
81-3	Acute inhalation, toxicity, rat						N/A	
81-4	Primary eye irritation, rabbit						N/A	
81-5	Primary dermal irritation						N/A	
81-6	Dermal sensitization						N/A	

BELL LABORATORIES, INC.
3699 Kinsman Boulevard
Madison, WI 53704

CORRESPONDENCE

§61-3 Discussion of formation of ingredients: N/A
Reference Technical Sodium Diphacinone data. The ingredients in the finished product consist of food stuffs; see Confidential Statement of Formula.

§62-1 Preliminary Analysis: N/A
Reference Technical Sodium Diphacinone data. The ingredients in the finished product consist of food stuffs; see Confidential Statement of Formula.

§63-5 Melting Point: N/A
This requirement is not applicable since finished product is a liquid.

§63-9 Vapor Pressure: According to Pesticide Assessment Guidelines Subdivision-D Product Chemistry, October 1, 1982, p. 69, Vapor pressure is required when the melting point of the pure form of the active ingredient in a product is equal to or less than 30°C. The melting point of the pure form of the product's active ingredient, Sodium Diphacinone is >220°C. Reference Sodium Diphacinone data.

§63-10 Dissociation Constant: N/A
Reference Technical Sodium Diphacinone data for the pure grade of the active ingredient to support end-use product.

§63-11 Octanol/Water Partition Coefficient: N/A
Reference Sodium Diphacinone data. This active ingredient is a sodium salt, not a non-polar organic. Reference Pesticide Assessment Guidelines Subdivision D, Product Chemistry, Oct. 1, 1982, page 70.

§63-14 Oxidizing/Reducing reaction: N/A
The finished product is not an oxidizer or reducer; it contains a simple non-reactive sodium salt and the balance is food stuffs.

§63-15 Flammability: N/A
The product contains [redacted]. Reference Confidential Statement of Formula.

§63-16 Explodability: N/A
The product [redacted]. Reference Confidential Statement of Formula.

Inert ingredient information may be entitled to confidential treatment

BELL LABORATORIES, INC.
3699 Kinsman Boulevard
Madison, WI 53704

§63-18 Viscosity: N/A
The finished product contains [redacted]. All other inerts and the active ingredient are water soluble, not a suspension: The percentage of solutes is low enough not to significantly change the viscosity of this product from that of water.

§63-19 Miscibility: N/A
Product's directions for dilution is with water, not petroleum solvents. (Reference Pesticide Assessment Guidelines, Subdivision D, Product Chemistry, October 1, 1982, p. 75.)

§63-20 Corrosion Characteristics: The product is a non-corrosive sodium salt solution of a non-reactant organic molecule.

§63-21 Dielectric breakdown voltage: N/A
The product is not intended for use in or around electrial equipment. (Reference Pesticide Assessment Guidelines Subdivision - D Product Chemistry, October 1, 1982, pg. 76.)

§81-1 Reference the cited public literature for Acute Oral Toxicity - Rat for Diphacinone:

Acute Oral LD50, rat = 2.3 mg/kg
The Pesticide Manual, 8th edition, publ. British Crop Protection Council.

27 JUN 1990

161/13 243899/2

Certified Mail

Ms Victoria J Kriesel
Bell Laboratories, Inc
3699 Kinsman Boulevard
Madison, Wisconsin 53704

Dear Ms Kriesel

Subject: Liqua-Tox II
EPA File Symbol 12455-AR
Your letter Dated May 1, 1990

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is not acceptable for the reasons given below.

1. Review of efficacy data (MRID 414718) cannot be completed at this time. To enable review of these data to be completed, you must.

   a. describe the procedures used to determine how readings were taken from calibrated bottles, indicate how amounts consumed were determined, and state whether readings or calculated values were written on the form "DAILY FOOD CONSUMPTION FOR RATS & MICE;"

   b. Describe the exact procedures use to prepare bait from concentrate, indicating amounts of each substance used and providing the results of a chemical analysis of the test bait for concentration of active ingredient.

2. Describe the containers (inner and outer) in which this product is to be packaged.

57988:I:A-5:Palmateer:M-13:KENCO:06/21/90:08/21/90:ka:sw:dd:ka

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

EPA Form 1320-1 (12-70)

OFFICIAL FILE COPY

3. Revise the directions for use on the product label to read as follows:

"DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS: This product may be used to control Norway rats (Rattus norvegicus), roof rats (R. rattus), and house mice (Mus musculus) in homes; in industrial, agricultural, and commercial buildings; and in similar manmade structures. Place LIQUA-TOX II in locations not accessible to children, pets, domestic animals, and nontarget wildlife, or in secured, tamper-proof bait stations equipped for dispensing liquid rodenticide baits. Do not use LIQUA-TOX II in any area where there is a possibility of contaminating food or surfaces that come in direct contact with food.

MIXING DIRECTIONS: Thoroughly mix contents of one 1.68 fl. oz. package in 1 quart (32 fluid ounces) of water.

SELECTION OF TREATMENT AREAS: Determine areas where rats and mice will most likely find and consume bait. Generally, these areas are along walls, by gnawed openings, beside burrows, in corners and concealed places, between floors and walls, or in other locations where signs of rats and mice have been seen.

APPLICATION DIRECTIONS:

Norway Rat and Roof Rat: Provide a minimum of 1 pint (16 fluid ounces) of LIQUA-TOX II in each dispenser (suitably-equipped bait station, chick fount, or other suitable device). If infested area is large, or if rat population appears to be high, use dispensers at several locations. Space dispensers and refill them as needed to ensure that bait is exposed in all infested areas where it can be used without putting nontarget organisms at risk.

House Mouse: Provide 1/2-pint (8 fluid ounces) placements of LIQUA-TOX II in suitably-equipped bait stations, chick founts, or other appropriate vessels. Place dispensers at intervals of 8-12 feet in all infested areas where bait can be used without putting nontarget organisms at risk.

Additional Directions for Rats and Mice: Replace contaminated or spoiled bait immediately. Collect and properly dispose of dead animals and bait that is no longer needed. Continue treatments as long as target species are being controlled by bait and nontarget species are not at risk.

4. Your Confidential Statement of formula (CSF) dated May 1, 1990 is not acceptable for the following reasons:

   A The registration number of the manufacturing use product (MUP) was not listed. If this product is not listed you will be required to supply all the data to support the registration of the MUP. Please clarify!

   B Please submit a manufacturers safety data sheet for [redacted]

5. We note you are using the Selective Method of data support. You will need to submit a data matrix. Please note that product chemistry and toxicology data is also required.

Pursuant to 40 CFR 152.105, if the above requested information, or a written request for additional time is not submitted to the Registration Division within 75 days of the date of the receipt of this notice, the application will be administratively withdrawn. In that event, any subsequent submission relating to the same product must be submitted as a new application.

If you have any questions about this letter, contact Steve Palmateer at (703) 557-4408 or 557-2600.

Sincerely yours,

William H. Miller
Product Manager (16)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

WATER SOLUBLE

Liqua-Tox®

(liquid concentrate)

DIPHACINONE
RODENTICIDE CONCENTRATE

Mix contents of pouch with 1 quart of water.

ACTIVE INGREDIENT:	
Sodium Salt of Diphacinone — 2-Diphenylacetyl-1,3-indandione	0.106%
INERT INGREDIENTS	99.894%
TOTAL	100.00%

CAUTION

KEEP OUT OF REACH OF CHILDREN

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION

Keep away from children, pets, and domestic animals and wildlife. Do not expose bait where humans, livestock, poultry, pets or wildlife can drink it. Treated baits should be placed in locations not accessible to children, pets, wildlife, domestic animals, or in tamper-proof bait boxes. Do not contaminate water by cleaning of equipment, or disposal of wastes. Apply this product only as specified on this label.

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If swallowed by humans, domestic animals, or pets, this material may reduce the clotting ability of the blood and cause bleeding. In such case intramuscular and oral administrations of Vitamin K_1 combined with blood transfusions are indicated as in the case of hemorrhage caused by overdoses of bishydroxcoumarin.

DIRECTIONS

HOW TO PREPARE: Dissolve contents in one quart of water. Pour liquid bait into glass, plastic or crockery dishes or chicken founts. Note: Metal containers are not recommended.

HOW TO USE: Place bait in locations where rats and mice feed and travel. Baiting should be maintained continuously as long as any evidence of feeding is observed.

FOR RATS: Minimum of one pint of liquid should be placed in several locations, such as, along walls, in corner, and where they can drink unobserved. Liquid stations should be maintained in an uninterrupted supply for at least 10 days.

FOR MICE: Minimum of one pint of liquid should be placed in several locations, such as, along walls, in corners, and where they can drink unobserved. Liquid stations should be maintained in an uninterrupted supply for at least 15 days.

IMPORTANT

Bait placements should be examined regularly and replenished before completely empty. Should baits become sour or moldy, they must be replaced. Where reinfestation is likely, permanent bait stations should be used and bait placed in them as often as necessary.

STORAGE AND DISPOSAL

STORAGE: Store only in original container, in a dry place inaccessible to children and pets.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Triple rinse (or eqivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

EPA Est. No. 12455-WI-1

NET CONTENTS: 1.68 Fl. Oz. (49.68 ml.)

IRB BRANCH REVIEW - TSS

Record Number(s)

263899

IN 5/9/90 OUT 6/19/90

EFFICACY

FILE OR REG. NO. 12455-AR

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED 5/2/90

DATE OF SUBMISSION 5/1/90

DATE SUBMISSION ACCEPTED 5/9/90

TYPE PRODUCTS(S): I, D, H, F, N, R, S (x)

DATA ACCESSION NO(S). 414718-02, 414718-01

PRODUCT MGR. NO. 16

PRODUCT NAME(S) LIQUA-TOX II

COMPANY NAME Bell Laboratories, Inc.

SUBMISSION PURPOSE registration

CHEMICAL & FORMULATION 1.06% Sodium Salt of Diphacinone liquid concentrate

Efficacy Review: LIQUA-TOX II, 12455-AR
Bell Laboratories, Inc.
Madison, WI 53704

200.0 INTRODUCTION

200.1 Uses

A 1.06% Sodium Salt of Diphacinone liquid concentrate proposed for registration for mixing into water baits for control of unspecified types of rats and mice "in locations where rats and mice feed and travel."

200.2 Background Information

See product jacket. Although there have been two prior submissions for this product, the current submission is the first that has been routed for an efficacy review. This submission includes proposed labels, efficacy data, a Confidential Statement of Formula (CSF), assorted "transmittal documents, and a cover letter.

201.0 DATA SUMMARY

According to the CSF, the product contains an [redacted].

The efficacy studies were run by Bell at its Madison facilities. Test subjects were Wistar strain laboratory Norway rats and Swiss Webster strain laboratory house mice. Tests were said to have been run according to EPA's Protocols 1.201 and 1.202 for rats and mice, respectively. In the rat test, there was a minor deviation from protocol which was caused by the breaking of a calibrated water bottle seven days into the study. As a result, only five bait and five water bottles were used for the eight remaining days of the study.

Comparisons of the "raw" data sheets with typed and tabulated results suggests that different methods were used for determining the amount of bait consumed in the rat and mouse tests. In the rat tests, the handwritten entries on the form entitled "DAILY FOOD CONSUMPTION FOR RATS & MICE" correspond to the typed entries for the respective bottle and day on the form entitled "Rodenticide Acceptability Assay Daily Feed Consumption." I was surprised by this fact because I expected that the numbers on the "DAILY

FOOD" form would be readings of the amount of liquid remaining. I suspected that amounts consumed would be determined by subtracting final values from the initial values (which were fixed at 100). It appears that just such a procedure was used for the mouse studies. Why the rat data were recorded differently than the mouse data is not clear. It appears that the studies were run by different technicians. It is possible that the lab director allows technicians some leeway in the methods used for recording results. It also is possible that the "raw" data sheets for rats were created/recreated after the second-and third-order data sheets were developed.

Reported test results are summarized in Table 1. These data suggest that the product would be very effective in controlling house mice and marginally effective in controlling Norway rats. Acceptance of bait made from the concentrate remained relatively high for the first eight days that mice were exposed to it (Fig. 1). All 20 mice died. In the rat trials, Acceptance peaked on the second day and dropped sharply thereafter (Fig. 2). Two of the three animals that survived the exposure period survived the entire test. Whether these animals learned to avoid the liquid bait or whether they never liked it in the first place cannot be determined from the test data because the animals were exposed as a group.

At this point, I am inclined to ask for more information on the way in which the amounts of liquid consumed were measured and recorded in both tests. Bell's reply might indicate whether Bell did done anything improper in conducting these studies.

The label submitted on 6/23/88 (in product jacket) bears the brand name "LIQUA-TOX II," but the label in the current submission bears the name "LIQUA-TOX," which is the name of Bell's Sodium Salt of Warfarin bait (12455-22). Curiously, the label submitted on 5/1/90 seems to be much more archaic in text than is the label last accepted for 12455-22 (on 12/8/82). In fact, 12455-22 never had accepted labeling corresponding to that just submitted for 12455-AR.

The text proposed for 12455-AR is very similar to that on the last accepted label for 3240-17 (a 1.06% Sodium Salt of Diphacinone concentrate registered by Motomco, Ltd., a firm affiliated with Bell), although some of the text in the "CAUTION" section has been updated.

TABLE 1. RESULTS OF GROUP-CAGED LABORATORY EFFICACY TESTS OF LABORATORY RATS AND MICE WITH 12455-AR

SPECIES [TEST #]	STRAIN	TEST DAY	g. BAIT TAKEN	g. CONTROL TAKEN	% BAIT ACCEPTANCE	DEATHS Males	DEATHS Females	DEATHS Total	PERCENT MORTALITY
Norway Rat 1089/B107	Wistar	1	279	370	43.0%	0	0	0	0.0%
		2	506	246	67.3%	0	0	0	0.0%
		3	294	383	43.4%	0	0	0	0.0%
		4	133	291	31.4%	2	1	3	15.0%
		5	48	159	23.2%	1	4	8	40.0%
		6	49	136	26.5%	3	0	11	55.0%
		7	9	126	6.7%	4	1	16	80.0%
		8	0	98	0.0%	0	1	17	85.0%
		9	4	91	4.2%	0	0	17	85.0%
		10	8	99	7.5%	0	0	17	85.0%
		11	1	87	1.1%	0	0	17	85.0%
		12	1	94	1.1%	0	0	17	85.0%
		13	14	90	13.5%	0	0	17	85.0%
		14	2	78	2.5%	0	0	17	85.0%
		15	2	67	2.9%	0	0	17	85.0%
		OBS.				0	1	18	90.0%
		ALL	1350	2415	35.9%	10	8	18	90.0%
House Mouse 0290/B108	Swiss Webster	1	91	43	67.9%	0	0	0	0.0%
		2	57	26	68.7%	0	0	0	0.0%
		3	55	13	80.9%	4	0	4	20.0%
		4	28	4	87.5%	2	3	9	45.0%
		5	5	3	62.5%	0	2	11	55.0%
		6	3	2	60.0%	0	1	12	60.0%
		7	1	1	50.0%	1	2	15	75.0%
		8	3	3	50.0%	2	1	18	90.0%
		9	0	0	----	1	0	19	95.0%
		10	1	0	100.0%	0	1	20	100.0%
		ALL	244	95	72.0%	10	10	20	100.0%

FIGURE 1. Daily bait acceptance and cumulative mortality in house mouse test with Liqua-Tox II.

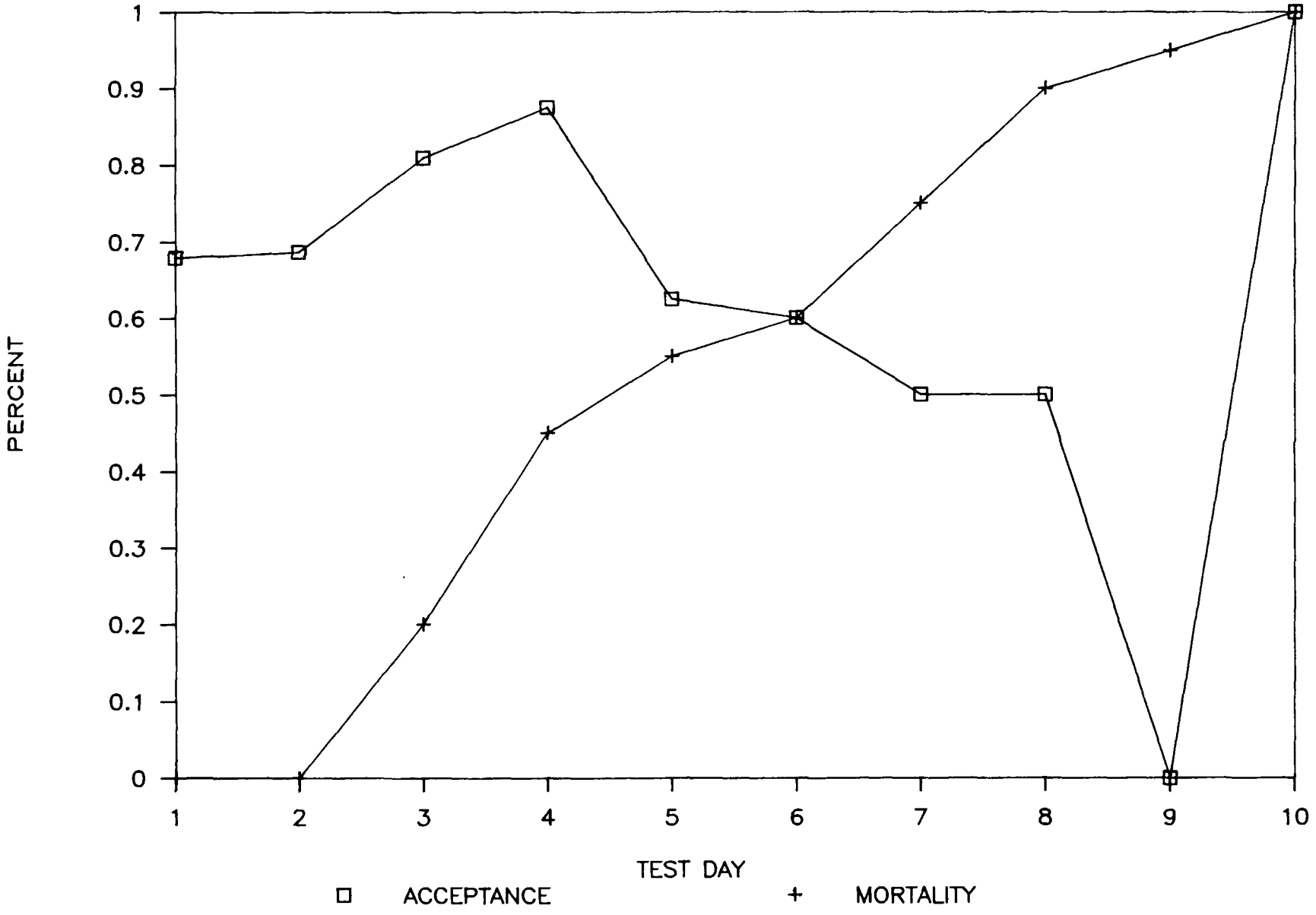
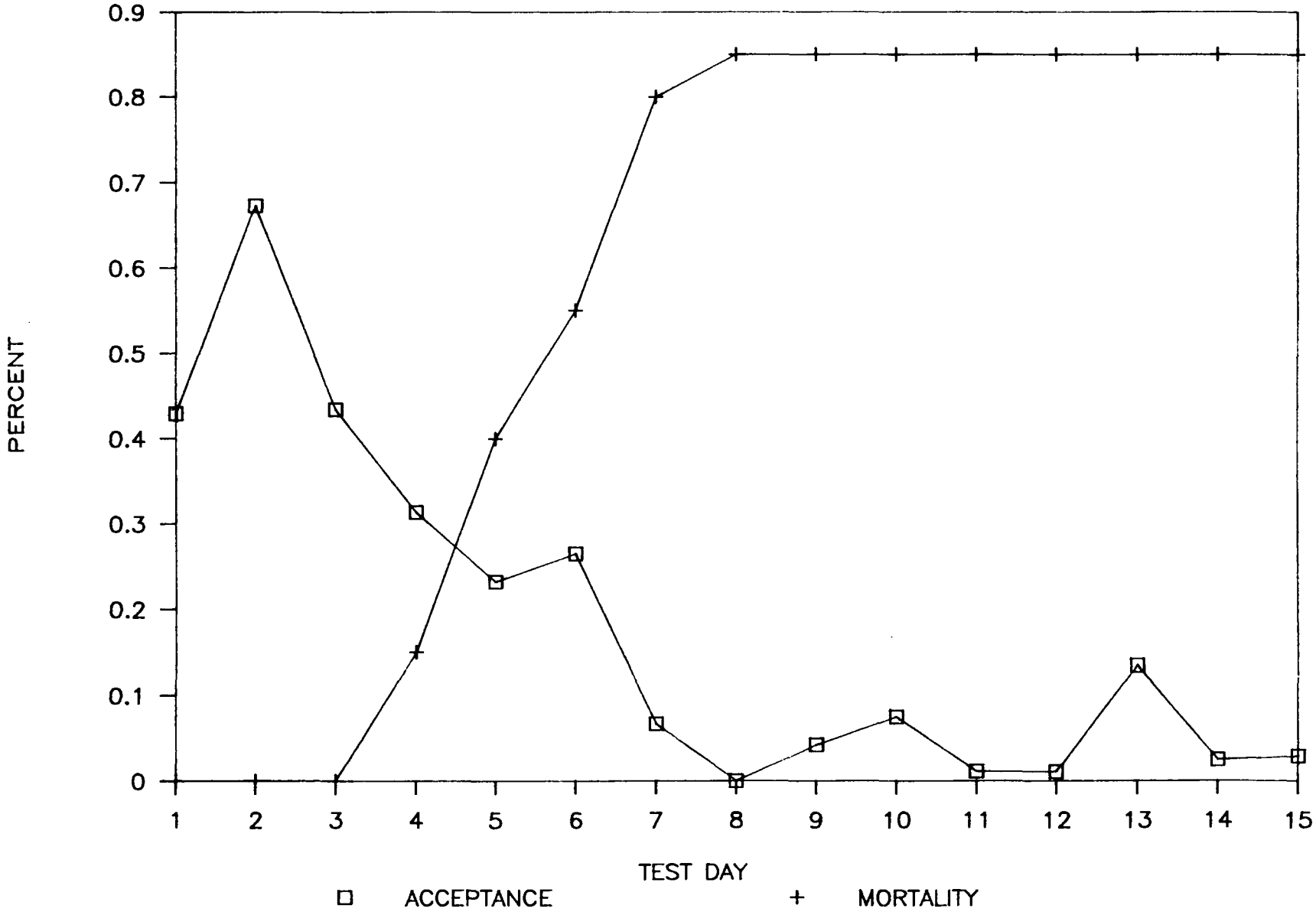


FIGURE 2. Daily bait acceptance and cumulative mortality in Norway rat test with Liqua-Tox II.



Following the mixing instructions proposed for 12455-AR in the label submitted 5/1/90 would appear to yield a liquid bait about three times as strong as that which would be obtained if the directions for 3240-17 were followed. The label previously submitted for 12455-AR claimed only one third as high a Diphacinone concentration in the product as did the label submitted of 5/1/90 yet the mixing directions were identical on the two labels. The reports of the efficacy trials state that the tests were initiated in October of 1989 and that the liquid concentrate was "mixed according to label directions to obtain a finished bait." It is not clear which set of mixing directions were used to prepare the test bait.

202.0 CONCLUSIONS

1. Review of efficacy data cannot be completed at this time. To enable review of these data to be completed, you must

   a. describe the procedures used to determine how readings were taken from calibrated bottles, indicate how amounts consumed were determined, and state whether readings or calculated values were written on the form "DAILY FOOD CONSUMPTION FOR RATS & MICE;"

   b. Describe the exact procedures use to prepare bait from concentrate, indicating amounts of each substance used and providing the results of a chemical analysis of the test bait for concentration of active ingredient.

2. Describe the containers (inner and outer) in which this product is to be packaged.

3. Revise the directions for use on the product label to read as follows:

"DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS: This product may be used to control Norway rats (Rattus norvegicus), roof rats (R. rattus), and house mice (Mus musculus) in

homes; in industrial, agricultural, and commercial buildings; and in similar manmade structures. Place LIQUA-TOX II in locations not accessible to children, pets, domestic animals, and nontarget wildlife, or in secured, tamper-proof bait stations equipped for dispensing liquid rodenticide baits. Do not use LIQUA-TOX II in any area where there is a possibility of contaminating food or surfaces that come in direct contact with food.

MIXING DIRECTIONS: Thoroughly mix contents of one 1.68 fl. oz. package in 1 quart (32 fluid ounces) of water.

SELECTION OF TREATMENT AREAS: Determine areas where rats and mice will most likely find and consume bait. Generally, these areas are along walls, by gnawed openings, beside burrows, in corners and concealed places, between floors and walls, or in other locations where signs of rats and mice have been seen.

APPLICATION DIRECTIONS:

Norway Rat and Roof Rat: Provide a minimum of 1 pint (16 fluid ounces) of LIQUA-TOX II in each dispenser (suitably-equipped bait station, chick fount, or other suitable device). If infested area is large, or if rat population appears to be high, use dispensers at several locations. Space dispensers and refill them as needed to ensure that bait is exposed in all infested areas where it can be used without putting nontarget organisms at risk.

House Mouse: Provide 1/2-pint (8 fluid ounces) placements of LIQUA-TOX II in suitably-equipped bait stations, chick founts, or other appropriate vessels. Place dispensers at intervals of 8-12 feet in all infested areas where bait can be used without putting nontarget organisms at risk.

Additional Directions for Rats and Mice: Replace contaminated or spoiled bait immediately. Collect and properly dispose of dead animals and bait that is no longer needed. Continue treatments as long as target species are being controlled by bait and nontarget species are not at risk.

William W. Jacobs
Principal Specialist: Rodenticides
Insecticide-Rodenticide Branch
June 19, 1990

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

MAY 09 1990

BELL LABORATORIES
3699 KINSMAN BLVD.
MADISON, WI 53704

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 05/02/90. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be substantially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exception(s) noted below. A copy of your bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each docu- ment submitted. Please use these numbers in all future references to these documents, and correct the noted exception(s) in future data submittals. If deficiencies were found which apply to your overall submission, they are described following this paragraph. If the defic- iencies apply to specific studies, they are listed below following the applicable identification number or MRID. Thank you for your cooperation. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

MRIDS 41471801 - 41471802 were all found to be deficient for the following reason/s:

A statement of compliance or non-compliance with the Good Laboratory Practices Standards contained in 40 CFR 160 is required for all studies (except range finding studies and supplements to previously submitted studies) submitted to EPA. This statement must appear as page 3 of all studies, and must be signed by the study sponsor, the study submitter, and the study director. Please see 40 CFR 160.12 for specific guidance.

414718-00

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER

Bell Laboratories, Inc.
3699 KInsman Blvd.
Madison, WI 53704

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

EPA File Symbol 12455-AR
158.160
96-10

TRANSMITTAL DATE

April 30, 1990

LIST OF SUBMITTED STUDIES

Volume 1: Administrative Materials

41471801 Volume 2: Efficacy Data, Swiss Webster Mice

41471802 Volume 3: Efficacy Data, Wistar Rats

Company Official: Victoria J. Kriesel

Victoria J. Kriesel

Company Name: Bell Laboratories, Inc.

Company Contact: Victoria J. Kriesel (608) 241-0202
Name Phone

Bell Laboratories, Inc.
3699 Kinsman Boulevard, Madison, Wisconsin 53704 U.S.A. / 608/241-0202 / Fax: 608/241-9631

May 1, 1990

FEDERAL EXPRESS
#6134613564

Mr. William H. Miller
Product Manager (16)
Office of Pesticide Programs-H7505C
U.S. Environmental Protection Agency
401 M. Street, Southwest
Washington, D.C. 20460

RE: LIQUA-TOX II
EPA File Symbol 12455-AR
Your Letter Dated November 28, 1989

Dear Mr. Miller:

Enclosed please find five copies of new draft labeling, a Confidential Statement of Formula, and three copies of efficacy data in support of the above mentioned product.

If you should have any questions regarding this matter, please do not hesitate to contact us.

Sincerely,

Bell Laboratories, Inc.

Victoria J. Kriesel

Victoria J. Kriesel
Registration Specialist

VJK:pml

Enclosures

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

28 NOV 1989

161 254,780 2
30

Bell Laboratories, Inc.
3699 Kinsman Boulevard
Madison, WI 53704

Gentlemen:

Subject: LIQUA-TOX II
EPA File Symbol 12455-AR
Your Letter Dated October 2, 1989

Your extension to pursue registration for Liqua-Tox II until May 1, 1990 has been granted. However, pursuant to Section 152.105 of Title 40 of the Code of Federal Regulations, the Agency will terminate any action on this application and will treat the application as if it has been withdrawn by you, unless by May 1, 1990 you submit the information as required.

If this cannot be done by May 1, 1990, then you must notify the Agency specifically what date the information will be provided.

Should the Agency treat your application as withdrawn, any subsequent submission relating to the same product must be submitted as a new application which will be subjected to the Agency's process of screening for completeness.

Sincerely yours,

William H. Miller

William H. Miller
Product Manager (16)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

56484:I:Cromwell:CBI-09:KENCO:11/17/89:1/3/90:dg:sw:vo:ek:dg

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

EPA Form 1320-1 (12-70) OFFICIAL FILE COPY

Bell Laboratories, Inc.
3699 Kinsman Boulevard, Madison, Wisconsin 53704 U.S.A. / 608/241-0202 / Fax: 608/241-9631

October 2, 1989

CERTIFIED MAIL
P 918 087 161

Mr. William H. Miller
Product Manager (16)
Office of Pesticide Programs-H7505C
U.S. Environmental Protection Agency
401 M. Street, Southwest
Washington, D.C. 20460

RE: LIQUA-TOX II
EPA File Symbol 12455-AR
Your Letter Dated August 8, 1989

Dear Mr. Miller:

Thank you for your letter concerning the above mentioned product.

Please be advised that we intend to pursue registration for LIQUA-TOX II.

However, we kindly request a six month extension. We are currently reviewing our initial submission, and will be submitting a slight change in the formulation.

Therefore, the time extension will give us ample time to submit new efficacy data as well.

Thank you for your cooperation in this matter.

Sincerely,

Bell Laboratories, Inc.

Victoria J. Kriesel

Victoria J. Kriesel
Registration Specialist

VJK:pml

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

08 AUG 1989

Bell Laboratories, Inc.
3699 Kinsman Blvd.
Madison, WI 53704

Subject: Proposed Product Name: Sequa-TOX II
File Symbol: 12455-AR

Our records for the subject product show that you have not responded to the attached letter. Therefore, pursuant to 40 CFR 152.105, the Agency will terminate any action on this application and will treat the application as if it has been withdrawn by you, unless within 75 days from the date of this letter you either submit the information as required by the attached letter of if this can not be done within the 75 day period then you must notify the Agency specifically what date the information will be provided.

Should the Agency treat your application as withdrawn, any subsequent submission relating to the same product must be submitted as a new application which will be subjected to the Agency's process of screening for completeness of application.

You should also be aware that the Agency may have revised the registration requirements since the attached letter was written.

If you have any questions regarding this letter, please contact William H. Miller at 703) 557-2600.

Sincerely yours,

William H. Miller

William H. Miller
Product Manager (16)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

U. S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

160 226128
10
11-18-88

BELL LABORATORIES
3699 KINSMAN BLVD.
MADISON, WI 53704

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 06/27/88. Our staff has completed a preliminary analysis of the material. The results are provided as follows.

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

The rejected documents below are identified with numbers which correlate to those taken from your submitted bibliography.

(01)

* You failed to sign the statement of data confidentiality claims included in the study.

Data Requirement Listings, Data Call-In Coversheets, EPA form 8570-1 and labels are considered to be administrative material rather than data and should not be bound as part of a study.

Daniel B. Peacock

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER

BELL LABORATORIES, INC.
3699 Kinsman Blvd.
Madison, WI 53704

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

12455 -
158.160
96-10

TRANSMITTAL DATE

June 23, 1988

LIST OF SUBMITTED STUDIES

Water Soluble Diphacinone (Liqua-Tox II)

EFFICACY DATA:

(01)

1) Swiss Webster Mice

2) Wistar Rats

Company Official: L. Dawn Brown _____

Company Name: Bell Laboratories, Inc.

Company Contact: L. Dawn Brown (608) 241-0202
NAME PHONE

WATER SOLUBLE

Liqua-Tox II

(liquid concentrate)

DIPHACINONE
RODENTICIDE CONCENTRATE

Mix contents of pouch with 1 quart of water.

ACTIVE INGREDIENT:	
Sodium Salt of Diphacinone-(2-diphenylacetyl-1,3-indandione)	0.0356 %
INERT INGREDIENTS	99.9644 %
TOTAL	100.0000 %

CAUTION

KEEP OUT OF REACH OF CHILDREN

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION

Keep away from children, pets, domestic animals and wildlife. Do not expose bait where humans, livestock, poultry, pets or wildlife can drink it. Treated baits should be place in locations not accessible to children, or pets, wildlife and domestic animals, or in tamper-proof bait boxes. Do not contaminate water by cleaning of equipment, or disposal of wastes. Apply this product only as specified on this label.

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If swallowed by humans, domestic animals or pets, this material may reduce the clotting ability of the blood and cause bleeding. In such case intravenous and oral administrations of Vitamin K_1 combined with blood transfusions are indicated as in the case of hemorrhage caused by overdoses of bishydroxycoumarin.

EPA Est. No. 12455-WI-1 EPA Reg. No.

NET CONTENTS: 1.68 Fl. Oz. (49.68 ml.)

DIRECTIONS

HOW TO PREPARE: Dissolve contents in one quart of water. Pour liquid bait into glass, plastic or crockery dishes or chicken founts. Note: Metal containers are not recommended.

HOW TO USE: Place bait in locations where rats and mice feed and travel. Baiting should be maintained continuously as long as any evidence of feeding is observed.

FOR RATS: Minimum of one pint of liquid should be placed in several locations, such as, along walls, in corner, and where they can drink unobserved. Liquid stations should be maintained in an uninterrupted supply for at least 10 days.

FOR MICE: Minimum of one pint of liquid should be placed in several locations, such as, along walls, in corners, and where they can drink unobserved. Liquid stations should be maintained in an uninterrupted supply for at least 15 days.

IMPORTANT

Bait placements should be examined regularly and replenished before completely empty. Should baits become sour or moldy, they must be replaced. Where reinfestation is likely, permanent bait stations should be used and bait placed in them as often as necessary.

STORAGE AND DISPOSAL

STORAGE: Store only in original container, in a dry place inaccessible to children and pets.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Triple rinse (or eqivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

United States Environmental Protection Agency
Washington, DC 20460

EPA Certification with Respect to Citation of Data

Form Approved
OMB No. 2070-0060
Approval expires 9-30-90

Applicant's Name and Address	EPA File Symbol/Registration Number
Bell Laboratories, Inc. 3699 Kinsman Blvd. Madison, WI 53704	12455-AR(61)
	Product Name LIQUA-TOX II
	Date of Application June 23, 1988

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product or of any other product that is identical or substantially similar, and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application.

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study, I am the original data submitter, or have obtained the written permission of the original data submitter to cite that study.

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study:

I am the original data submitter; or I have obtained the written permission of the original data submitter to cite that study; or

I have notified in writing the companies who have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act; and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: *(Check one)*

☐ All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method). *(Also sign the General Offer to Pay Statement below.)*

☒ Those companies who have submittted the studies which I have cited (Selective method).

Signature	Name and Title	Date
L. Dawn Brown	L. Dawn Brown Manager Research & Dev.	6/23/88

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required by FIFRA sec. 3(c)(1)(D) and 3(c)(2)(D).

Signature	Name and Title	Date
L. Dawn Brown	L. Dawn Brown Manager Research & Dev.	6/23/88

EPA Form 8570-29 (7-86)

Form Approved. OMB No. 2070-0060. Approval expires 9-30-90.

EPA

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAM (TS-767)
WASHINGTON, D.C. 20460

APPLICATION FOR PESTICIDE: [X] REGISTRATION [ ] AMENDMENT A

Please read instructions on reverse before completing.

SECTION I

1. COMPANY/PRODUCT NO.	2. DATE	3. PRODUCT MANAGER	4. PROPOSED CLASSIFICATION
12455-AR(61)	June 23, 1988	W. Miller	[X] GENERAL [ ] RESTRICTED

5. NAME AND ADDRESS OF APPLICANT *(Include ZIP Code)*

Bell Laboratories, Inc.
3699 Kinsman Blvd.
Madison, WI 53704

[ ] CHECK IF THIS IS A NEW ADDRESS

6. PRODUCT NAME
LIQUA-TOX II

SECTION II

1. SUBJECT OF AMENDMENT

[ ] RESUBMISSION IN RESPONSE TO AGENCY LETTER DATED _____

[ ] FINAL PRINTED LABEL IN RESPONSE TO AGENCY LETTER DATED _____

[ ] OTHER *(explain below)*

SECTION III

1. WILL THIS PRODUCT BE PACKAGED IN:

CHILD-RESISTANT PACKAGING [ ] YES [X] NO

UNIT PACKAGING [X] YES [ ] NO
If YES, unit pkg. wt. 1.7 oz No. per container 50

WATER-SOLUBLE PACKAGING [ ] YES [X] NO
If YES, pkg. wt. _____ No. per container _____

2. TYPE OF CONTAINER
[ ] METAL
[X] PLASTIC
[ ] GLASS
[ ] PAPER
[ ] OTHER *(Specify)*

3. LOCATION OF NET CONTENTS
[X] LABEL [ ] CONTAINER

4. SIZE(S) OF RETAIL CONTAINER
1.7 oz X 50

5. LOCATION OF LABEL DIRECTIONS
[X] ON LABEL
[ ] ON MATERIAL ACCOMPANYING PRODUCT

6. MANNER IN WHICH LABEL IS AFFIXED TO PRODUCT
[ ] LITHOGRAPH [X] OTHER *(Specify)*
[ ] PAPER GLUED Label is printed on a plastic
[ ] STENCILED pouch that is the container.

SECTION IV

1. CONTACT POINT *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application).*

NAME
L. Dawn Brown

TITLE
Manager Research & Development

TELEPHONE NO. *(Include Area Code)*
608-241-0202

2. SIGNATURE
L. Dawn Brown

3. TITLE
Manager R & D

4. TYPED NAME
L. Dawn Brown

5. DATE SIGNED
6/23/88

6. DATE APPLICATION RECEIVED *(Stamped)*

EPA Form 8570-1 (Rev. 5-81) PREVIOUS EDITION IS OBSOLETE.

INSTRUCTIONS

GENERAL

This form is to be used for all applications for new and amended registrations for pesticide products.

In order to process an application for new registration submitted on this form, the following material must accompany the application:

1. Offer to Pay Statement (EPA Form 8570-22, -23, or -24). *(If not exempted by 40 CFR 162.9-1(b).*
2. Confidential Statement of Formula (EPA Form 8570-4).
3. Five copies of draft labeling.
4. Three copies of any data submitted.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8 1/2 x 11 inch paper or as a mock-up of the proposed label. If prepared as a mock-up it should be constructed in such a way as to facilitate storage in an 8 1/2 x 11 inch file. Mock-up labels significantly smaller than 8 1/2 x 11 inches should be mounted on 8 1/2 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in three copies. In order to facilitate review, each type of data submitted must be bound separately, and clearly identified on the front cover including the date submitted.

A copy of the application form and a copy of the label should be bound in each separate volume of the data.

ALL DATA FOR WHICH CLAIMS OF CONFIDENTIALITY ARE ASSERTED MUST BE SUBMITTED, BOUND SEPARATELY AND CLEARLY MARKED AS SUCH.

SPECIFIC

Please read the instructions listed below before completing this application. First determine the type of registration action, listed in BLOCK A, for which you are submitting this application. For applications submitted in connection with NEW REGISTRATION actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, Section I, II, and IV must be completed by the applicant.

BLOCK A - Check the appropriate action for which you are submitting this form.

Section I - This Section must be completed for both REGISTRATION and AMENDED REGISTRATION actions.

1. Company/Product Number - Insert your company number, if one has been assigned. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If application is for an amendment, insert the registration number of the product.
2. Date - Fill in the appropriate date.
3. Product Manager - If known, fill in the name and number of the Product Manager.
4. Proposed Classification - Specify the proposed classification for this product.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters.

   An applicant NOT residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

AMENDMENT INFORMATION

Section II - This Section must be completed for all applications submitted in connection with AMENDED REGISTRATION.

1. Subject of Amendment - Check the appropriate block, and provide a brief explanation of the purpose(s) for the amendment, such as: "the addition a site, pest, or crop"; "to change inert ingredient"; "general label revisions of precautionary statements", etc.

PACKAGING AND CONTAINER INFORMATION

Section III - This Section must be completed for all applications submitted in connection with NEW REGISTRATION.

1. Type of Packaging - Check the appropriate block if you product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Indicate the location of the statement of net contents.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Direction - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicate the method product labeling is attached to retail container

CONTACT POINT

Section IV - This Section must be completed for all REGISTRATION and AMENDED REGISTRATION applications.

1-5. Self-explanatory.

6. EPA Use Only.

Bell Laboratories, Inc.
3699 Kinsman Boulevard, Madison, Wisconsin 53704 U.S.A. / 608/241-0202 / Telex:910-286-2775
Rodent MDS
Fax: 608/241-9631

June 23, 1988

FEDERAL EXPRESS
3313879321

Mr. William H. Miller
Product Manager (16)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)
Environmental Protection Agency
Crystall Mall, Bldg. 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

SUBJECT: LIQUA-TOX II
EPA File Symbol: 12455- AR(61)

Dear Mr. Miller:

Enclosed please find a completed EPA form 8570-1 Application for Pesticide for a New Product LIQUA-TOX II Rat and Mouse Bait. Additionally, please find five copies of draft labelling, a Confidential Statement of Formula, an Offer to Pay Statement, and three copies of efficacy data.

For this application, we would like to reference our Technical Diphacinone File, EPA Reg. No. 12455-25 for supporting data.

Thank you for your assistance.

Sincerely,

Bell Laboratories, Inc.

L. Dawn Brown
Manager of Research & Development

LDB:pml

enclosure

Pages 182-185*Confidential Statement of Formula may be entitled to confidential treatment*